

From: Max Katz
To: Henry, Howard
Date: 1/17/2005 8:12:09 AM
Subject: Re: Production Update

Howard,

Good Job! Thanks for seeing this through.

Max

>>> Howard Henry 1/14/2005 11:47:13 PM >>>

Good evening, This evening Andrew Abatangelo and Scott Graney informed me that the CTC was shutting down for an Exhaust Air Temperature Alarm issue. The unit was kept in pause mode for 10 hrs during the temperature/humidity excursion issues in the area. This may have contributed to the problem. After inspecting the unit, it appeared that a coil was not emitting enough heat. Instrumentation mechanic Ben Tibay was paged, inspected the unit and adjusted the face and by-pass dampers. The by-pass valve for the inlet coil was also opened. The system coating processed was resumed however the exhaust temp still dropped. Various other parts of the system were checked. Finally, Jerry Rosado recalled hearing a noise in the exhaust section of the coater. After inspection, a plate was found unbolted. The plate was reinstalled and coating resumed at 10:50 pm. WO# 469834 was issued for this job. I would like to thank Jerry for noticing and pinpointing the trouble area, Ben Tibay for his diligent effort helping to troubleshoot the entire system and Joe Piscino and Jim Tonner for their conscientious assistance. Secondly, Susan Lindland requested that weigh door 112A/560, which was stuck in the open position, be checked. After inspecting the door, the door could be closed manually, however it still was not functional. Security was contacted and supervisor Jerry Perioli sent an electrician to the area to access the situation. After inspecting the door, Jerry stated that an electrician from Consumer Health would have to be contacted for electrical schematics to fix the door. Instrumentation Mechanic Ben Tibay accessed the situation and stated that the door would have to be fix by a carpenter. An attempt will be made to have a Consumer Health electrician and a carpenter fix the door. WO# 469835 was issued for this job. Have a good weekend and please contact me if you have any questions. Please feel free to forward this message to individuals inadvertently not on the "To" list who may need to know this information. Thank you, Howard Henry Howard Henry

Production Engineer
Wyeth Pharmaceuticals
Consumer Health Division
401 N. Middletown Rd.
Pearl River, NY 10965
(845)-602-4843- Office
(845)-602-3181-Fax

CC: Espejo, Andrew

From: Andrew Espejo
To: Henry, Howard
Date: 1/17/2005 7:58 AM
Subject: Re: Production Update
CC: Katz, Max

Howard,
Thanks for sticking with this one. It is greatly appreciated.
Andrew

>>> Howard Henry 1/14/2005 11:47:13 PM >>>

Good evening,

This evening Andrew Abatangelo and Scott Graney informed me that the CTC was shutting down for an Exhaust Air Temperature Alarm Issue. The unit was kept in pause mode for 10 hrs during the temperature/humidity excursion issues in the area. This may have contributed to the problem. After inspecting the unit, it appeared that a coil was not emitting enough heat. Instrumentation mechanic Ben Tibay was paged, inspected the unit and adjusted the face and by-pass dampers. The by-pass valve for the inlet coil was also opened. The system coating processed was resumed however the exhaust temp still dropped. Various other parts of the system were checked. Finally, Jerry Rosado recalled hearing a noise in the exhaust section of the coater. After inspection, a plate was found unbolted. The plate was reinstalled and coating resumed at 10:50 pm. WO# 469834 was issued for this job. I would like to thank Jerry for noticing and pinpointing the trouble area, Ben Tibay for his diligent effort helping to troubleshoot the entire system and Joe Piscino and Jim Tonner for their conscientious assistance.

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Have a good weekend and please contact me if you have any questions. Please feel free to forward this message to individuals inadvertently not on the "To" list who may need to know this information.

Thank you,
Howard Henry
Howard Henry
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Wyeth

Due Date Extension

OPEN PRs; PRs ASSIGNED TO ME

Commitment - Pearl River Pharmaceuticals (PRP)

PR	Assigned To	Status	Date Due	Original Due Date	Days Extended	Time	Days	Days	Short Description
74115	Espejo, Andrew [7]	CMT in Progress	2005-06-30	3/31/2005	91	1	214	(44)	Move all inventory from PTS program to Maximo
81831	Espejo, Andrew [2]	CMT in Progress	2005-08-31	3/31/2005	153	1	148	(106)	Complete 21 CFR Part 11 Remediation Plan for Fette 3200 Tablet Presses
83040	Espejo, Andrew [3]	CMT in Progress	2005-07-01	4/29/2005	63	1	131	(45)	Tablet Hoes <i>extended</i>
89211	Espejo, Andrew [4]	CMT in Progress	2005-05-31	Same	0	0	88	(14)	Screen with Smaller Holes for 8K
90042	Espejo, Andrew [5]	CMT in Progress	2005-05-24	Same	0	0	82	(7)	Evaluate feasibility of re-engineering the lock-in pin on valve <i>extended</i>
92297	Espejo, Andrew [6]	CMT in Progress	2005-08-31	Same	0	0	68	(106)	Parts Storage attendants need to be trained on missing requirements
100180	Espejo, Andrew [7]	CMT in Progress	2005-06-10	Same	0	0	19	(24)	Evaluation for Inspecting Hardness Testers <i>Max</i>
100240	Espejo, Andrew [8]	CMT in Progress	2005-10-28	Same	0	0	19	(164)	Create job plan for tooling on Stokes compression machines in manufacturing
101318	Espejo, Andrew [9]	CMT in Progress	2005-06-03	Same	0	0	12	(17)	Update FRMs 00000602, 00000615 and 00001400 <i>Chen</i>
Total number of items per Quality System: 9									5/17/05

From: Howard Henry
To: Espejo, Andrew
Date: 5/18/2005 1:31:36 PM
Subject: Re: Commitments Due

Good afternoon Andrew,

I reviewed the commitment list you forwarded this morning. Since this was the first time I was made aware of the items due in June, completing the tasks associated with PR# 101318 specifically by the original due date is not feasible. Furthermore, I need clarification on each of these commitments (PR# 100180 & PR# 101318) so that action items may be selected and executed properly, to obtain the desired result.

In the future, I would like an opportunity to discuss the purpose and goal of a commitment. This establishes an overall scope so that action items may be selected and performed correctly.

All too often a rush ensues to meet an imposed deadline, only to correct errors on items missed, at a later date, resulting from the hurried situation. Implementing this review process should minimize the need to correct missed items.

Thanks and have a good day,
Howard

>>> Andrew Espejo 5/17/2005 5:41:04 PM >>>

Please attached list of due commitments with responsible parties. Please ensure that all commitments are closed before their respective due dates.

Thanks,
Andrew

ENGINEER STATUS PROJECT REPORT

WCH Centrum Production (PPU#1)

August 31, 2005

Project	Date Received	Purpose	Task Description/Progress	Status
CTC System Improvements	Ongoing	Perform all duties in order to successfully maintain and enhance the operation of the CTC system.	<p>The following tasks must be performed in order improve or enhance the process:</p> <ol style="list-style-type: none"> 1. Batch Accountability: Implemented a procedure to produce results that are within specifications, for all batches of a weekly CTC campaign using the CTC Weigh belt: <ul style="list-style-type: none"> • 3/7/05: Meeting held. Attendees: Farooq Moatter (QA), J. Hibbert (Manufacturing), A. Espejo (Manufacturing), W. Wardrop (Manufacturing), H. Henry (Manufacturing). Procedure to get a "system full weight" and to use the last bin of a batch outlined and agreed upon. Will be done for both Centrum® (Product Code: 04451) and Centrum® Silver (Product Code: 04463). <ul style="list-style-type: none"> ◦ Centrum® study plan protocol: 640-0002-CI-41 "Theoretical System Full Weight": <ol style="list-style-type: none"> i. Approved: 3/14/2005 ii. Executed: 3/21/2005 <ol style="list-style-type: none"> 1. Results: 123.0 kg iii. Implemented: 4/05 ◦ Centrum® study plan protocol: 640-0002-CI-42 "End of Batch Determination": <ol style="list-style-type: none"> i. Approved: 3/14/2005 ii. Training: 4/11/05 iii. Executed: 4/05 iv. Implemented: ◦ Centrum® Silver study plan protocol: 640-0002-CI-27 "Theoretical System Full Weight": <ol style="list-style-type: none"> i. Approved: 3/14/2005 ii. Executed: 3/15/2005 <ol style="list-style-type: none"> 1. Results: 122.0 kg iii. Implemented: 5/05 ◦ Centrum® Silver study plan protocol: 640-0002-CI-28 "End of Batch Determination": <ol style="list-style-type: none"> i. Approved 3/14/2005: 	<ol style="list-style-type: none"> 1) Status for each item is listed below: <ul style="list-style-type: none"> ▪ Complete. Processes implemented 5/05

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Howard Henry
Process Engineer III
Manufacturing

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		<p>ii. Executed:</p> <p>iii. Implemented:</p> <ul style="list-style-type: none"> • Emailed forwarded to commence operator training. Scheduled for April 7, 2005. (4/5/05) • Trained all shifts. Came in @ 11:00 pm to perform a special training for the midnight shift (4/11/05) • Trained QA personnel on the new procedure. Attendees: J. Rivera, L. Gubala, M. Szutkowski, and K. Dillon. • Change control submitted to implement End of batch change for CTC after 4 weeks of good results. The results for the last batch of each weekly campaign are as follows: <ul style="list-style-type: none"> ◦ Week of (14 batches): 	
<p>MIR Commitments</p>	<p>Ongoing</p>	<p>Various commitments received during various production excursions</p>	<p>1. PR #81993 "Complete 21 CFR Part 11 System Remediation Plan for Continuous Coater #1 and #2 PRP039, PRP040.</p> <ul style="list-style-type: none"> • Due date: 3/31/2005 • Completed the following deliverables: <ul style="list-style-type: none"> ◦ Validation Plan summary document (7 page document) ◦ PPG-00022214 "Maintenance and System Administration Procedure Continuous Tablet Coater, CTC Number 1 and Number 2", 31-page document. ◦ Approval of User Requirements Specifications "Compu-Coat 5 Control Systems for the Continuous Tablet Coaters (CTC #1 and #2) 35 page document: (Approved 3/30/05) ◦ Revision of PPG 00010967 "Operation of Single Pass Continuous Tablet Coater System in Manufacturing" (Approved 3/30/2005) <p>2. PR #82074 "Install storage shelves for cleaning agents in common areas (PPU#1)</p> <ul style="list-style-type: none"> • Due date: 4/30/2005 ◦ Originally given to J. Fleming ◦ Obtained WO from Jim to close commitment.
			<p>1. Complete (PR# 81993).</p> <ul style="list-style-type: none"> • Closed (3/30/05) <p>2. Complete (PR# 82074).</p> <ul style="list-style-type: none"> • Closed (4/21/05))

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			<p>5. PR #90042: Evaluate the feasibility of re-engineering the lock-in pin on valve</p> <ul style="list-style-type: none"> • Due date: 9/20/05 <ul style="list-style-type: none"> ◦ Vendor contacted to provided plan and quote to redesign the valve ◦ 7/26/05: Quote received. ◦ Vendor contacted about quote. ◦ 8/2/05: Memo written assessing quote and feasibility of proposed redesign. ◦ Documents submitted for closure (8/3/05). <p>6. PR #107328: Evaluate possibility of putting door sweep on doors</p> <ul style="list-style-type: none"> • Due date: 9/08/05 <ul style="list-style-type: none"> ◦ Discussed situation with F. Erichsen. ◦ WO# 1087975 initiated to investigate if this request is possible. ◦ Work Complete: 7/18/05 ◦ Closure documents submitted: 7/19/2005 <p>7. PR #111134: CTC By-Pass Training"</p> <ul style="list-style-type: none"> • Due date: 7/29/2005 <ul style="list-style-type: none"> ◦ Create slides for training operators on the functionality of the By-Pass, Resume and Pause modes for the coater (1.5 hr) ◦ All CTC operators trained on the By-Pass Training (7/21/05). <ul style="list-style-type: none"> ▪ Midnight shift: 6 am ▪ Day Shift: 7:30 am ▪ Afternoon Shift: 3:15 pm ◦ Iso-train documents scanned into Trackwise for closure. ◦ Forwarded and closed by QA (7/25/05) <p>8. PR #111136: CTC By-Pass Training"</p> <ul style="list-style-type: none"> • Due date: 8/31/2005 <ul style="list-style-type: none"> ◦ DCC Initiated. ◦ Document amended. Author and Business 	<p>5. Complete (PR# 90042).</p> <ul style="list-style-type: none"> • Closed (8/3/05) <p>6. Complete (PR# 107328).</p> <ul style="list-style-type: none"> • Closed (7/20/05) <p>7. Complete (PR# 111134).</p> <ul style="list-style-type: none"> • Closed (7/25/05) <p>8. Complete (PR# 111136).</p> <ul style="list-style-type: none"> • Closed (X/XX/05)
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MIR Commitments (Assistance)	Ongoing	Provide information to Compliance Specialists to close commitments and investigations generated in Trackwise.	<p>approval (8-5-05)</p> <ul style="list-style-type: none"> PPG forwarded to QA (8/05/05) <p>9. PR #113992: "PR #113992: Put WA# 60674 and WA# 60672 in "Idle" state via a change Control."</p> <ul style="list-style-type: none"> Due date: 11/14/2005 	<p>9. Complete (PR# 113992).</p> <ul style="list-style-type: none"> Closed (X/XX/05)
			<p>1. PR #87715 "Bag ripped while charging the 8K blender"</p> <ul style="list-style-type: none"> Bars cut. Work order initiated by J. Fleming CCP 2005-166 initiated to modify shaker Exhaust port truncated. Dump sink lowered, magnetic bar cut. Metal angle affixed to unit. Grounding cables inspected. <p>2. PR #87903 "Foreign object embedded in tablet during coating"</p> <ul style="list-style-type: none"> Gap fixed in Ajax Shaker. WO initiated by J. Fleming CCP 2005-166 initiated to modify shaker Exhaust port truncated. Dump sink lowered, magnetic bar cut. Metal angle affixed to unit. Grounding cables inspected. <p>3. PR #88309 "Paper found on Ajax shaker in 8K Blender"</p> <ul style="list-style-type: none"> Discussed situation with compliance specialist J. Hibbert. New screen ordered. 3/16" verses 1/4" plate will be tested. Will be installed under PR# 89211. CCP 2005-510 initiated to install the screen 6/29/05; Screen test successful. CCP 2005-0637 initiated to change the SOI. <p>4. PR #87903 "Foreign object embedded in tablet during coating"</p> <ul style="list-style-type: none"> Gap fixed in Ajax Shaker. WO initiated by J. Fleming CCP 2005-166 initiated to modify shaker Exhaust port truncated. Dump sink lowered, magnetic 	<p>Assistance provided to successfully close and complete investigations.</p>

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				<p>bar cut. Metal angle affixed to unit. Grounding cables inspected.</p> <p>5. PR #91760: CTC Leaky Gun Issue (3/21/05).</p> <ul style="list-style-type: none"> Due date: 4/08/05 <ul style="list-style-type: none"> Batch# 4451-A82020, Drums 29 – 37 experienced wet tablets. Approx. ½ hr discussion. Provided root cause analysis information to Compliance Specialist Jacqui Hibbert. <p>6. PR #93618: PC#7: Pan #3 wasted due to eroded tablets.</p> <ul style="list-style-type: none"> Due date: 4/16/05 (For March attainment 3/31/05) <ul style="list-style-type: none"> Batch# 08427-A73880, Pan wasted due to eroded tablets. Initiated WO# 488056 to Investigate situation. Provided Compliance Specialist Jacqui Hibbert with a copy of the work order and copy of e-mail message stating the original situation. Explained work done on work order. Requested closed WO from maintenance. WO signed closed out. Copied of WO faxed and given to J. Hibbert (3/29/05). <p>7. PR #97737: OOT for Hardness Tester WA# 17037, PMO# 59381.</p> <ul style="list-style-type: none"> Due date: 5/13/05 <ul style="list-style-type: none"> Initiated by maintenance engineer Ark Maciak. Provided Compliance Specialist Jacqui Hibbert with Maximo screen print showing equipment location. Explained OOT history. Contacted A. Maciak for a copy of the last calibration to show equipment was functional prior to the OOT (0.25hr) Instructed R. Harms to enter late data entries in the logbook for the scale. Provided J. Hibbert with scale information for missing months; Sept. 2004, Feb-2005 and Mar. 2005.
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| <p>8. PR #98017: Scale not working WA# 36193 possible OOT.</p> <ul style="list-style-type: none"> • Due date: 5/15/05 <ul style="list-style-type: none"> ◦ Initiated by maintenance engineer Ark Maciak. ◦ Provided Compliance Specialist Jacqui Hibbert with Maximo screen print showing equipment location. ◦ Explained OOT history. Contacted M. Aboyoun of last calibration to show equipment was functional prior to the last failure (0.5hr) <p>9. PR# 98906: PC#7: Centrum Export Low Silicon for several pans.</p> <ul style="list-style-type: none"> • Due date: 5/21/05 <ul style="list-style-type: none"> ◦ Initiated WO#489350 for PC#7 and WO#489362 for PC#8. Instrumentation Mechanics inspected the unit. Unable to find the problem. Contacted maintenance to have the manufacture visit the plant. ◦ Vector visited plant. Found damper not functioning repaired under WO# 489350. ◦ System check. Unit functioning properly. <p>10. PR #103762: Batch#: 04451-B05224, Incorrect recipe used.</p> <ul style="list-style-type: none"> • Due date: 6/17/05 <ul style="list-style-type: none"> ◦ Wrong recipe chosen by operator B. Shand during the processing of a Centrum Production batch on 5/18/2005. ◦ Reviewed the both recipes with compliance specialist J. Hibbert. ◦ Explained the difference between the Centrum® Silver End of Batch Recipe and the Centrum® Film Coated Tablets Recipe in order to close the investigation. Since the unit did not spray, there was no product impact. ◦ Described the solution application process regarding the amount of solution sprayed by out-feed guns and in-feed guns. Although the recipes had different values (e.g. in-feed Centrum® film coated = 1300 gm/min vs. in- |
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3333			<p>feed Silver end of batch = 1350 gm/min), the total amount of solution sprayed by both in-feed and out-feed guns = 2750 gm/min, is the same for both coaters.</p> <ul style="list-style-type: none"> o Analyzed and clarified the recipe regarding why the coater kept shutting down when this recipe was chosen and answered questions on the likelihood of pan rotation for each time the unit shutdown. o Based on explanation, the MIR classification was changed to an ERF. <p>11. PR #104490: PO# A69593: Splice Detector Malfunction</p> <ul style="list-style-type: none"> • Due date: 6/22/05 <ul style="list-style-type: none"> o Work order initiated by R. Kressler, WO# 1010613. o Searched for WO copy at the request of Compliance Specialist J. Hibbert. o Wrong WO# provided. Correct WO# 1080613. o Work request found. Copy provided to J. Hibbert to close investigation. <p>12. PR #104743: OOS 2.526% gain in CTC coating (4451-B05233) & PR# 106698: OOS 2.217% gain on the 6th batch of a 12-batch string.</p> <ul style="list-style-type: none"> • Responsible Person: J. Hibbert <ul style="list-style-type: none"> o During the week of 5/23/05, a gain of 2.526%, obtained for the second batch of a 14-batch campaign. o Explained new procedure to J. Hibbert. o Provided suggestions and theories of what may have caused the OOS values. o Belt theory used to close the commitment. o 6/17/05: Explained Theory to K. Dillon (1 hr) o 6/21/05: Tour conducted with K. Dillon and J. Hibbert. Explained all possible reasons for gain. (1.5 hr) o 6/23/05: Emailed message sent to the supervisors, cc. J. Hibbert & A. Espejo outlining the criteria to vacuum & inspect the Weigh belt.
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Howard Henry
Process Engineer III
Manufacturing

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WCH Centrum Production (PPU#1)

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			<p>13. PR #110548: OOT found for pressure transducer WVA# 95959</p> <ul style="list-style-type: none"> • Responsible Person: J. Hibbert <ul style="list-style-type: none"> ◦ Explained situation to J. Hibbert. Described the functionality of the pressure transducer. ◦ Explained how there was no batch impact (0.75 hr). ◦ 7/6/05: Explained atomizing air concept to J. Hibbert. (0.25hr) <p>14. PR #109691: Brown tablets found in packaging for batch processed in CTC#2</p> <ul style="list-style-type: none"> • Responsible Person: J. Deutchman <ul style="list-style-type: none"> ◦ 6/28/05: J. Deutchman explained that a batch was left in the CTC for approximately 7 hrs. S. Graney provided and explanation. Did not make sense. Took J. Deutchman to the coater to show how the unit functions. Explained the difference between when the coater is in pause mode versus having the unit in resume mode. Check the by-pass functionality of the unit. Most Probable Cause (MPS), unit left in resume mode and not pause mode causing the moisture for the AHU to damage the tablets. (1.0 hrs) ◦ Commitments will be initiated to add steps to the SOP and to train the operators on the difference. 	<p>1) Change complete: (0741) Work complete: X/XX/05 Closure docs submitted: X/XX/05 CCP Closed: X/XX/2005</p>
<p>Change Control Procedures</p> <p>3334</p>	<p>Ongoing</p>	<p>Initiation, Closure and Cancellation of Change Control Procedures</p>	<p>1) CCP 2005-0741: "Hardness Testers: Salvage and Departmental equipment ownership changes.</p> <ul style="list-style-type: none"> • Emergency request by F. Moatter (7/28/05) • Initiated: 7/29/2005. • G. Keaney stated testers WVA# 14056, 13999, and 14070 must be recalibrated prior to use. WO# 1104030, 1104026, 1104225 Initiated. • Approved: • Closure due date: 	

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Manufacturing

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<p>2) CCP 2005-0672 "Ajax Shaker" Buna-N Nitrile Rubber. Specifying that the material is food grade.</p> <ul style="list-style-type: none"> Initiated: 7/07/2005. Verbal approval (7/6/2005)-G. Keaney Approved: 7/11/2005 Closure due date: 11/11/2005 	<p>2) Change complete: (0672) Work complete: 7/05/05. WCC closed 7/27/2005 Closure docs submitted: 7/28 CCP Closed: 7/29/2005</p>
<p>3) CCP 2005-0662: "Change SOI to read 3/16" plate from it reading a 1/4" plate." Done for Centrum® Export and Centrum® Silver Accela-Coater and Pan Coater batches.</p> <ul style="list-style-type: none"> Initiated: 7/06/2005 Approved: 7/21/2005 Closure due date: 9/21/2005 	<p>3) Change complete: (0662) Closure docs submitted: X/XX CCP Closed: X/XX/2005</p>
<p>4) CCP 2005-0637: "Change SOI to read 3/16" plate from it reading a 1/4" plate."</p> <ul style="list-style-type: none"> Initiated: 6/29/2005 ("RUSH" CCP submitted) Walked document around for signatures Approved: 7/1/05 E-mail sent for formula SOI change approval (8/2/2005) Closure due date: 8/03/2005 	<p>4) Change complete: (0637) Formula approved: 8/02/05 Closure docs submitted: 8/03 CCP Closed: 8/03/2005</p>
<p>5) CCP 2005-0584 "Chute modifications for press WA# 33192 and 34887"</p> <ul style="list-style-type: none"> Work orders WO# 108777 and 1087779 submitted to shorten chutes. QA requested a change control to documents the change. Chutes shortened from 13.5" to 7.5" Initiated: 6/10/2005 (Emergency CCP submitted) Change implemented 6/9/05 QA approval 6/10/05 (G. Keaney). Approved: 6/20/2005 Closure due date: 9/20/2005 	<p>5) Change complete: (0584) Work complete: 6/8/05 Closure docs submitted: 6/27 CCP Closed: 6/30/2005</p>
<p>6) CCP 2005-0583 "Temporary Monitor replacement for Fette Press WA# 33192"</p> <ul style="list-style-type: none"> Initiated: 6/6/2005 (Emergency CCP submitted) QA approval 6/5/05 (G. Keaney). 	<p>6) Change complete: (0583) Work complete: 6/8/05 Closure docs submitted: 6/22 CCP Closed: 6/30/2005</p>

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Process Engineer III
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WCH Centrum Production (PPU#1)

August 31, 2005

			<ul style="list-style-type: none"> • Approved: • Closure due date: 7/20/2005 		
		<p>7) CCP 2005-0510 "Installation of 3/16" Screen for Ajax Shaker"</p> <ul style="list-style-type: none"> • Initiated: 5/20/2005 (Emergency CCP submitted) • CCP walked around. Approved in one day. • Approved: 5/20/2005 • Original closure due date: 6/3/2005 • Screen too big, must be resized. Explained situation to F. Moatter. • Extension request for 3 months forwarded 6/1/05. • Closure due date: 8/31/2005 	<p>7) Change complete (0510) Work complete: 6/29/2004 Closure docs submitted: 7/15 CCP Closed: 7/21/2005</p>		
		<p>8) CCP 2005-0473: "CTC End of Batch Procedure-Accountability."</p> <ul style="list-style-type: none"> • Initiated: 05/12/2005 • Approved: 05/13/2005 • Closure due date: 6/13/2005. 	<p>8) Change complete. (0473) Closure docs submitted: 6/3 CCP Closed: 6/6/2005</p>		
		<p>9) CCP 2005-0397 "Stokes 754 Motor Change"</p> <ul style="list-style-type: none"> • Initiated: 04/07/2005 (Emergency CCP submitted) • Approved: 04/18/2005 • Closure due date: 7/18/2005. 	<p>9) Change complete. (0397) Closure docs submitted: 7/15. CCP Closed: 7/18/2005</p>		
		<p>10) CCP 2005-0394 "Comprima Project: WA# request"</p> <ul style="list-style-type: none"> • Initiated: 04/15/2005 (Emergency CCP submitted) • Approved: 04/18/2005 • Closure due date: 10/18/2005. 	<p>10) Change complete. (0394) Closure docs submitted: X/XX CCP Closed: X/X/2005</p>		
		<p>11) CCP 2005-0255: "Designate scales WA# 16966 and WA# 35088 portable equipment in Maximo and on each PMO document."</p> <ul style="list-style-type: none"> • Initiated: 03/04/2005 (Emergency CCP submitted) • Approved: 03/23/2005 • Closure due date: 6/30/2005. • Document amended on 03/21/05 to add a statement 	<p>11) Change complete. (0255) Closure docs submitted: 6/28 CCP Closed: 6/28/2005</p>		

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			<ul style="list-style-type: none"> describing scale use and designation. Closure due date: 6/30/2005 					<p>12) Change complete: (0167) Closure docs submitted: 4/27/2005 CCP Closed: 5/9/2005</p>
			<p>12) CCP 2005-0167: "Fike pressure sensor relocation-Littleford-8K".</p> <ul style="list-style-type: none"> Emergency Change control initiated: (2/17/05) QA approval given by G. Kearney Submitted: 2/17/2005 Approved: 2/18/2004 Closure due date: 5/31/2005 					<p>13) Change complete: (0166) Closure docs submitted: 4/27/2005 CCP Closed: 5/9/2005</p>
			<p>13) CCP 2005-0166: "Ajax Shaker Modifications".</p> <ul style="list-style-type: none"> Emergency Change control initiated: (2/17/05) QA approval given by G. Kearney Submitted: 2/17/2005 Approved: 2/18/2004 Closure due date: 5/31/2005 					<p>14) Change complete: (0165) Closure docs submitted: 4/27/2005 CCP Closed: 5/9/2005</p>
			<p>14) CCP 2005-0165: "Product Collector Door installation W/A# 93533".</p> <ul style="list-style-type: none"> Emergency Change control initiated: (2/17/05) QA approval given by G. Kearney Submitted: 2/17/2005 Approved: 2/18/2004 Closure due date: 5/18/2005 					<p>15) Change complete: (1470) Closure docs submitted: 1/28/2005. Air Balance report resubmitted 2/02/05. CCP Closed: 2/9/2005</p>
			<p>15) CCP 2004-1470: "Bin Storage Project Construction".</p> <ul style="list-style-type: none"> Change control Initiated: (10/22/05) Submitted: 10/22/2005 Approved: 10/26/2004 (Phase I) Approved: 11/05/2004 (Phase II) Closure due date: 2/25/2005 					<p>16) Change complete: (1419) 12/07/2004 Closure docs submitted: 12/7 CCP Closed: 12/7/2004</p>
			<p>16) CCP 2004-1419 "Temporary Monitor replacement for Fette Press W/A# 33192"</p> <ul style="list-style-type: none"> Initiated: 10/12/2004 (Emergency CCP submitted). QA approval 10/11/05 (F. Moatter). Submitted: 10/12/2004 Approved: 10/18/2004 					

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SOP Initiation & Revision	1/04	Initiate and revise SOPs as needed	<ul style="list-style-type: none"> • Closure due date: 4/30/2005 17) CCP 2004-1404 "Additional Coil for CTC#2 AHU WA# 35463" <ul style="list-style-type: none"> • Initiated: 10/11/2004 • QA approval 10/11/05 (F. Moatter). CCP walked around and approved in one day. • Closure due date: 4/15/2005 18) CCP 2004-1168: "Comprima Project-Modification of Compression Room W (112-310)" <ul style="list-style-type: none"> • Initiated: 8/16/2004 (Joe Torres) • Approved plan: 8/23/2004 • Approved start construction: 9/28/2004 • Approve to use: 11/15/2004 • Approved to use filters: • Original closure due date: 3/1/2005 • Amendment closure due date: 7/18/2005 	<p>17) Change complete. (1404) 11/2/2004. Validation doc approved 1/5/05. Closure docs submitted. 1/20/2005. Memo submitted 1/27/05 CCP Closed: 8/26/2004</p> <p>18) Change complete: (1168) Closure docs submitted: 7/15. Corrections needed. Resubmitted 7/18/05. CCP Closed: 7/18/2005</p>
<p>3338</p> <p>Howard Henry Process Engineer III Manufacturing</p>			<p>1. The SOP documents listed below are tracked monthly. The title and status is listed below:</p> <ul style="list-style-type: none"> • PPG-00001254 10K Littleford Blender, Loading Room, and Blending Room Cleaning. <ul style="list-style-type: none"> ◦ Target approval date: 5/15/2004 ◦ New FRM-00002686 approved 5/14/2004 ◦ Proposed effective date: 6/1/2004 ◦ Effective: 6/1/2004 • PPG-00000447 Cleaning of Tablet Blns equipped with Butterfly Valves. <ul style="list-style-type: none"> ◦ Target approval date: 8/20/2004 ◦ New FRM-00002689 approved 8/20/2004 ◦ Proposed effective date: 11/1/2004 • PPG-00000858 Vac-U-Max Cleaning <ul style="list-style-type: none"> ◦ Target approval date: 8/13/2004 ◦ New FRM-00002692 approved 8/13/2004 ◦ Proposed effective date: 11/1/2004. • PPG-00001480 Preparation of Aqueous Coating Solutions (Tanks with Silverson Mixers)/ 	<p>The status of each item is listed below:</p> <ol style="list-style-type: none"> 1. Painting SOP: <ul style="list-style-type: none"> ▪ Complete: Approved 1/30/04. ▪ Complete: Training done on 2/5/2004 2. IBEX Pump Form: <ul style="list-style-type: none"> ▪ Complete: Form approved 3/12/2004. Documents obsolete, effective 6/01/2004. 3. Document information and status is listed below each PPG or FRM.

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				<ul style="list-style-type: none"> ○ Target approval date: 7/16/2004 ○ New FRM-00002688 approved 7/15/2004 ○ Proposed affective date: 11/1/2004 • PPG-00001963 Vac-U Max Operation <ul style="list-style-type: none"> ○ Target approval date: 8/13/2004 ○ New FRM-00002692 approved 8/13/2004 ○ Proposed affective date: 11/1/2004 • PPG-00000517 Operation of Servo-Lift In Manufacturing <ul style="list-style-type: none"> ○ Target approval date: 5/30/2004 ○ New PPG-00015585 approved 5/27/2004 ○ Proposed affective date: 11/1/2004 • PPG-00000519 Operation of Servo-Lift In Manufacturing <ul style="list-style-type: none"> ○ Target approval date: 5/30/2004 ○ New FRM-00002688 approved 5/27/2004 ○ Proposed affective date: 11/1/2004 • PPG-00002216 Dornier Conveyor Belt Cleaning <ul style="list-style-type: none"> ○ Target approval date: 8/27/2004 ○ New FRM-00002687 approved 8/27/2004 ○ Proposed affective date: 12/1/2004 • PPG-00002220 Accurate Weigh Belt Cleaning <ul style="list-style-type: none"> ○ Target approval date: 8/27/2004 ○ New FRM-00002691 approved 8/26/ ○ Proposed affective date: 12/1/2004 • PPG-00002221 Coating Solution Tank Cleaning (Tanks with Silverson Mixers) <ul style="list-style-type: none"> ○ Target approval date: 8/6/2004 ○ New PPG-00002691 approved 8/6/2004 ○ Proposed affective date: 11/1/2004 • SOP 20296 Continuous Tablet Coater Cleaning in Manufacturing <ul style="list-style-type: none"> ○ Target approval date: 9/3/2004 ○ New FRM-00002694 approved 9/3/2004 ○ Proposed affective date: 12/1/2004 <p>2. Created Painting SOP for Painting Procedures in Manufacturing:</p> <ul style="list-style-type: none"> • Create SOP (PPG 00005683) and assessment
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	<p>confirm if this use required a change control.</p> <ul style="list-style-type: none"> Information acquired from Percy Boykin, Bob Hirsch and Brent Alderman regarding tube materials Vendor contacted. E-mail from vendor forwarded regarding CPA 90002543 (Nylo Seal Solution Hose 1/4"). Farooq Moatter contacted. Situation explained. Farooq stated no CCP needed. E-mail sent to group. 	
	<p>2. Production Tour Assistance.</p> <ul style="list-style-type: none"> Conducted four CTC tour presentations on 3/16/05 for the Cornell University MBA student's production tour. Assignment received the morning of 3/16/05. 	
	<p>3. SMED Team Participant.</p> <ul style="list-style-type: none"> Fette Critical Spare Parts List: <ul style="list-style-type: none"> i. Critical Spare parts list forwarded to group. <ul style="list-style-type: none"> Due date: 3/7/2005 Date submitted: 3/4/2005 ii. Fette Spare Parts list (3/22/05): Assignment given to forward a spare parts list with price, quantity in stock and minimum quantity needed, to M. Katz and A. Espejo by 3/30/05: <ul style="list-style-type: none"> a. 3/22/05: Reviewed list, accounted for parts in stock and established minimum part quantities that must be in stock. Done in conjunction with Tom Rock, Jim Fleming and Percy Boykin (1.5 hrs) b. 3/30/05: Met with Percy Boykin. Obtained price list information. Used detailed list information to find the price (3.5 hrs) c. Formulated list (1.0 hrs). List forwarded to M. Katz and A. Espejo 3/30/05 @ 8 pm. <ul style="list-style-type: none"> Due date: 3/30/2005 Date submitted: 3/30/2005 iii. Fette Spare Parts Inventory Meeting Scheduled for 4/19/05 @ 2:30 pm. Notice forwarded to the 	

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				<p>iv. CIP 100/200 for Clean in place unit</p> <p>5. Broken Tablet Committee (team member).</p> <ul style="list-style-type: none"> Comparison Study of Centrum® Silver and Centrum® Export <ol style="list-style-type: none"> Action item: Received 3/17/05 Since both products use the same equipment, outline the differences between the products for possible reasons for broken tablets. SOI documents for Centrum Silver and Export scrutinized. Results presented at 3/24/05 meeting. Conveyor Belt Memo: Potential source of broken tablets created due to improper inlet conveyor belt set up. Submit memo with comments and recommendations. <ol style="list-style-type: none"> Inlet conveyor scrutinized Operators and supervisors informed and alerted to the situation. Memo written and submitted Tablet Hoe implementation: <ol style="list-style-type: none"> Old tablet rake (hoe) design was heavy and could be breaking tablets Order new devices to reduce this occurrence. New devices ordered modified and placed on the floor. <p>6. Change Control Meeting coverage, review and signoff.</p> <ul style="list-style-type: none"> Represent operations for equipment/facility related changes. <ol style="list-style-type: none"> Coverage for the 5/23/05 meeting. Approximately 20 CCP documents reviewed. 6/30/05: Assisted Ms. Elke Morgan-Philips by reviewing and signing the following Change Control documents: <ol style="list-style-type: none"> CCP 2004-308-1 "Wrong Classification of Leak Detective I" CCP 204-1290-4, 2004-1412-4, 2004-1413-4, 2004-1567-5 Extensions for various pieces of
				<p>5. Broken Tablet Action items Status:</p> <ul style="list-style-type: none"> SOI comparison: documents reviewed. Raw materials for each compared. Information forwarded to Technology. Complete Conveyor belt memo: Complete. Tablet hoe implementation: Ongoing <p>6. Change Control Meeting Coverage Status:</p> <ul style="list-style-type: none"> Coverage provided. Complete

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			<p>equipment (FTIR and photo-spec units.)</p> <p>7. Centrum Millennium Project.</p> <ul style="list-style-type: none"> • Informed by A. Espejo will production representative for the project. <ul style="list-style-type: none"> i. Meeting scheduled: 6/30/05; Discussed project scope with Sridhar Venkatesan iii. 7/6/05: Preliminary testing scheduled. iv. Participated in conference call meetings <p>8. Protocol execution for Centrum (Protocol# 640-0002-CI-47) and Centrum Silver (Protocol# 645-0002-CI-31):</p> <ul style="list-style-type: none"> • Objective of protocol execution is to increase 15 min readings to 30 min. readings for compression using the Fette 3200 Tablet presses. <ul style="list-style-type: none"> i. Explained protocol to R. Morgan & J. Hallock ii. Execution 6/24/05 iii. 6/29/05: Check compression Room for protocol execution. Operator staff had difficulty executing the test. R. Morgan stated that two people would have to be assigned to the room to perform this task. Technology department (Sridhar Venkatesan) contacted. Two interns (Samantha Yacopino and Alejandro Perez) trained to help. <p>9. Risk Assessment Analysis for the CTC system:</p> <ul style="list-style-type: none"> • During a meeting held on Monday May 16th, A. Espejo requested that a risk assessment be performed on the CTC system if the system is not upgraded to Windows 2000 and made 21CFR Compliant. Results should be submitted by COB 5/18/05; <ul style="list-style-type: none"> • System assessment received from A. Morris via e-mail 5/17/05 • Information forwarded to A. Espejo on 5/18/05 @ 5:00 pm 	<p>7. Millennium Project Status:</p> <ul style="list-style-type: none"> • Ongoing <p>8. Protocol execution status:</p> <ul style="list-style-type: none"> • Complete <p>9. Risk Assessment Status:</p> <ul style="list-style-type: none"> • Complete
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Manufacturing Support	1/04	Provide general support to all areas throughout manufacturing	Continue to provide support to areas throughout the year performing the tasks listed below:	
			<p>1. Waste Reduction Team:</p> <ul style="list-style-type: none"> Room Log Request by Carlene Bassell. <ul style="list-style-type: none"> 3/8/2005: Room log copies for PC#7, #8, #9 and #10 forwarded to Carlene Bassell. Recommended the investigation of a local Dust collector used in compression. Possible dust explosion hazard. C. Bassell contacted me. DC removed. Dust explosion hazard found. 	<p>1. Waste Reduction Team Status:</p> <ul style="list-style-type: none"> Complete: Assistance provided.
			<p>2. Maintenance Zone Checklist:</p> <p>Assist supervisors in fulfilling the weekly requirement to analyze and repair areas for specific Maintenance zone assignments. Perform the following activities associated with this task:</p> <ul style="list-style-type: none"> Performed Internal Audits with supervisors in order to maintain Zone(s). Send notifications via e-mail regarding the completion of the zone checklists for Zones 3, 4, 10, 14, 27, 28, and 31. Enter work order numbers on forms and forward completed checklists to Communicate work order request number to supervisor so that number can be logged unto Zone Checklist form. 	<p>2. Maintenance Zone Status:</p> <ul style="list-style-type: none"> All action items performed weekly
			<p>3. Central Storage / Set-Up Shop Area Assistance:</p> <ul style="list-style-type: none"> Provided coverage of the compression shop area during the absence of supervisor Jim Fleming Assisted with Fette coverage as well as work order initiation. 	<p>3. Central Shop Assistance Status:</p> <ul style="list-style-type: none"> Complete assistance provided.
			<p>4. Blender Timer Printout Support (Provide printouts for non-legible readings for all equipment throughout the area equipped with Blender timers)</p> <ul style="list-style-type: none"> Littleford 8K Blender (3-11-05: 2 min blend) 	<p>4. Blender Support Status:</p> <ul style="list-style-type: none"> Ongoing. Printouts provided for supervisors from all three Trains

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- o Requested by: Sean McGarvey (3-14)
 - o Batch#: Centrum-8427-A74639
 - o Supplied: 3/15/05
- Littleford 8K Blender (3-11-05: 1 min blend)
 - o Requested by: Alice Gass (3-14)
 - o Batch#: Centrum-8427-A82117
 - o Supplied: 3/15/05
- Littleford 8K Blender (3-16-05: 10 min blend)
 - o Requested by: Sean McGarvey (3-16)
 - o Batch#: Centrum-4451-A82134
 - o Supplied: 3/17/05
- Littleford 8K Blender (3-16-05: 2 min blend)
 - o Requested by: Sean McGarvey (3-16)
 - o Batch#: Centrum-4451-A82134
 - o Supplied: 3/17/05
- Littleford 8K Blender (3-23-05: 12 min blend)
 - o Requested by: Sean McGarvey (3-23)
 - o Batch#: Centrum-4451-A99204
 - o Supplied: 3/29/05
- Littleford 8K Blender (3-23-05: 2 min blend)
 - o Requested by: Sean McGarvey (3-23)
 - o Batch#: Centrum-4451-A99204
 - o Supplied: 3/29/05
- Littleford 8K Blender (5-24-05: 10 min blend)
 - o Requested by: Alice Gass (6-07-05)
 - o Batch#: Centrum-4451-A097703
 - o Supplied: 6/08/05
- Littleford 8K Blender (5-24-05: 1 min blend)
 - o Requested by: Alice Gass (6-07-05)
 - o Batch#: Centrum-4451-A097703
 - o Supplied: 6/08/05
- Gemco 30: 130/510 (6-8-05: 40 min blend)
 - o Requested by: Skip Gremli (7-05-05)
 - o Batch#: Fibercon-2500-B04605
 - o Supplied: 7/07/05 -Blender in use 7/6/05 AM / PM Shifts. Down 7/7/05.
- Gemco 30: 130/510 (6-8-05: Blend Times: 5:42 pm - 6:21 pm)
 - o Requested by: Skip Gremli (7-05-05)

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			<p>5. Initiate Maximo requests throughout the plant for all areas.</p> <ul style="list-style-type: none"> Batch#: Fibercon-2500-B04603 Supplied: 7/07/05-Blender in use 7/6/05 AM / PM Shifts. Down 7/7/05. <p>Areas include but not limited to Bathrooms, Elevators, Hallways, all Mechanical Rooms, all Blending Rooms, all Coating areas and equipment, all Compression rooms and equipment, Inspection Areas, Warehouses, Washrooms, Weigh Rooms and Office Areas.</p> <ul style="list-style-type: none"> Attend weekly scheduling meetings for execution updates Clear all WQAR (Awaiting QA review) backlogs <p>6. Emergency Maintenance Response and Coverage:</p> <ul style="list-style-type: none"> CTC System Software Failure: <ul style="list-style-type: none"> Saturday, January 29th, 2005: Received page from Scott Graney providing details of the CTC system crash. Investigated system. In-house electrician could not be contacted. Outside electrician contacted. System could not be restored. 2/1/05: System partially restored 2/2/05: System restored 2/21/05: System inspected by Thomas Engineering. System disks will be provided. E-mail messages providing updates sent 1/31, 2/1 and 2/2/05. Littleford 8K Blender Fike Alarm Fault: <ul style="list-style-type: none"> Received page form Sean McGarvey explaining the Fike alarm fault IM Brent Alderman contacted. Could not fix system. Fike contacted Saturday, March 19, 2005: Fike rep. Rick Stedel on job site by 9:30 am 	<p>5. Status listed below:</p> <ul style="list-style-type: none"> Maximo requests are ongoing No WQAR backlog as of 8/05/05 <p>6. Status listed below:</p> <ul style="list-style-type: none"> Complete: System restored support provided. Complete: System restored support provided
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			<p>7. DI Water System Coverage:</p> <ul style="list-style-type: none"> Problem assessed and fixed by approximately 11:40 am Tasks: Issue work orders as needed. Perform Cl₂ and O₃ tests on system. Perform daily walk-through(s) of the area. Done twice in the am and pm. Perform RO, TOC, acid level checks. Daily system-log checks and sign offs <ul style="list-style-type: none"> System Coverage 3/23 – 3/29/05 <ul style="list-style-type: none"> Issued WO# 489216 to repair Loop#3 damaged O₃ sensor probe System Coverage 5/24 – 5/31/05. System Coverage 7/20 – 7/26/05 <ul style="list-style-type: none"> O₃ generator shutdown. WO# 1097661 issued; Compressed air line damaged. <p>8. WAPSOP SOP conversion assistance:</p> <ul style="list-style-type: none"> 5/19/05: Received folder from D. Lyons containing PPG-00001480 (Prep of Aqueous Coating Solution) for review. 5/20/05: Reviewed and returned to D. Lyons with comments. <p>9. Monthly PMO (Status and notification): Performed the following duties to complete this task</p> <ul style="list-style-type: none"> Create spreadsheet Track PMO completion sign off percentage <p>10. Littleford 8K and 10K Plough Repair Coverage:</p> <p>Provided coverage for both units during off hours in order to have ploughs repaired expeditiously, minimizing equipment downtime.</p> <ul style="list-style-type: none"> Littleford 10K Repairs: <ul style="list-style-type: none"> Ploughs ground down to repair wholes found in upper arc plate. Littleford 8K Repairs: 	<p>7. Status listed below:</p> <ul style="list-style-type: none"> Water system coverage provided <p>8. Status listed below:</p> <ul style="list-style-type: none"> Complete. <p>9. Status listed below:</p> <ul style="list-style-type: none"> Complete: Spreadsheet created each month. Progress tracked. <p>10. Status listed below:</p> <ul style="list-style-type: none"> Complete: Coverage provided.
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GMP and 21 CFR Part 11 Compliance	4/04	Evaluate equipment to insure that it is 21 CFR Part 11 Compliant (CTC)	<ul style="list-style-type: none"> • Provided coverage for plough repairs and communicated progress of repair to group. 	
		<p>The following tasks must be performed in order to complete this task:</p> <ol style="list-style-type: none"> 1. PPG-00022214 "Maintenance and System Administration Procedure Continuous Tablet Coater, CTC Number 1 and Number 2", 31-page document. <ul style="list-style-type: none"> • 3/15/05: Received document for review • Reviewed document on 3/15-17/2005. • Document review complete. Changes discussed with Part 11 consultant Ms. Andrienne Morris. Changes submitted. • Review due 3/18/05. Complete: 3/18/05. • 3/22/05: Review final changes with C. Defeciani and A. Morris (1.5 hrs) <ul style="list-style-type: none"> o Removed Change Control log and certain steps that were deemed unnecessary. 2. Amendment to PPG-00010697 "Operation of Single Pass CTC in Manufacturing" to meet 21CFR Compliance Standard <ul style="list-style-type: none"> • DCC submitted (3/17/05); DCC# RD2005-000242 • DCC approved (3/18/05) • Document revised and forwarded (3/18/05). • Assessment revised and forwarded (3/18/05) • Document review complete (3/23/05). • Assessment review complete (3/23/05) • Documents approved (3/30/05). • Documents effective (4/11/05). 3. Approval of User Requirements Specifications "Computer 5 Control Systems for the Continuous Tablet Coaters (CTC #1 and #2) 35 page document: <ul style="list-style-type: none"> • 3/18/05: Reviewed document with A. Morris (2 hrs). Discussed changes. Revisions made to pages 12, 22 (deleted FS-2085), 23, 31 and page 32. • Approved after revisions were made (3/18/05) • Reviewed and approved revisions to document. 	<ol style="list-style-type: none"> 1. Status listed below: <ul style="list-style-type: none"> • Complete: Document Reviewed. 2. Status listed below: <ul style="list-style-type: none"> • Project Completion Date: 3/31/05 • Project Complete: 3/30/05 via commitment PR# 69050 3. Status listed below: <ul style="list-style-type: none"> • Complete: Document Reviewed. 	

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	<p>Updated FS-3027 (3/28/05)</p> <p>4. Approval of Validation Plan summary document 7 page document:</p> <ul style="list-style-type: none"> Reviewed document (0.5 hrs). Revisions made and forwarded to A. Morris (3/30/05). Document approved and forwarded. (3/30/05). <p>5. Answered various vendor questions on Issues:</p> <ul style="list-style-type: none"> Emailed Andrienne Morris regarding system customization Reviewed documents Assessment Summary Form, a 25-page document and System Remediation Plan PRP039 and PRP040 (Document# ISSC04-180 Version#: 1.0), a 20-page document 3/16/05 <ul style="list-style-type: none"> Document resubmitted to manufacturing based on errors found within the documents. E-mailed Mr. Paul Lavella answering questions regarding the function, validation number(s) and a potential area walk through for chart recorders in the production area (3/22/05). Supplies copies of the System Configuration Screens for CTC#1 and CTC#2 for Ms. A. Morris, for the Design Specification Document ISSC04-360 (3/24/05). Performed walk through with contractors Paul Lavella and Ray Gollhue to verify chart recorder location (WA# 17420, 17171, 16879, 16298, 17278, 60510). Other recorders not on list found and verified (1hr). <p>6. CTC System Administration Tasks:</p> <ul style="list-style-type: none"> Trained on PPG-0002214 "System Administration and Maintenance Procedure. Email sent to officially grant access to the CTC system.
	<p>4. Status listed below:</p> <ul style="list-style-type: none"> Complete: Document Reviewed. <p>5. Status listed below:</p> <ul style="list-style-type: none"> Complete: Assistance provided. <p>6. Status listed below:</p> <ul style="list-style-type: none"> Ongoing

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GMP and 21 CFR Part 11 Compliance	4/04	Evaluate equipment to insure that it is 21 CFR Part 11 Compliant (Fette)	<p>The following tasks must be performed in order to complete this task:</p> <ol style="list-style-type: none"> 1. PPG-00022214 "Maintenance and System Administration Procedure Continuous Tablet Coater, CTC Number 1 and Number 2", 31-page document. <ul style="list-style-type: none"> • 3/15/05: Received document for review • Reviewed document on 3/15-17/2005. • Document review complete. Changes discussed with Part 11 consultant Ms. Andrienne Morris. Changes submitted. • Review due 3/18/05. Complete: 3/18/05. • 3/22/05: Review final changes with C. Defeciani and A. Morris (1.5 hrs) <ul style="list-style-type: none"> o Removed Change Control log and certain steps that were deemed unnecessary. • Email sent to officially grant access to the CTC system. 	<p>1. Status listed below:</p> <ul style="list-style-type: none"> • Ongoing
PMO Review and Remediation	10/04	Inspect PMO's to insure equipment is calibrated within user specifications and that the correct PMO frequency is used	<p>The following PMO's were inspected:</p> <ol style="list-style-type: none"> 1) PMO#44014: Weigh belt Feeder (Electrical) <ol style="list-style-type: none"> a. New equipment (WA# 86567) b. Received 10/15/04 (6 page document). c. Reviewed and forwarded to QA on 10/14/04. 2) PMO#44179: Weigh belt Feeder (Instrumentation) <ol style="list-style-type: none"> a. New equipment (WA# 86567) b. Received 10/15/04 (6 page document). c. Reviewed and returned on 10/14/04 3) PMO#44014: Weigh belt Feeder (Mechanical) <ol style="list-style-type: none"> a. New equipment (WA# 86567) b. Received 10/15/04 (10 page document). c. Reviewed and returned on 10/14/04 4) PMO#41184: Servo-lift (Mechanical) <ol style="list-style-type: none"> a. New equipment (WA# 89568) 	Ongoing

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				<p>devices.</p> <ul style="list-style-type: none"> d. Signed three MEIN forms initiated by M. Aboyoun. e. Reviewed and forwarded to QA on 3/09/05 <p>10) PMO# 47397: Scales (WA# 17456)</p> <ul style="list-style-type: none"> a. Removed scale from PMO 47397 as per CCP 2005-0345. b. Reviewed MEIN form initiated by M. Aboyoun. c. Signed and forwarded to QA on 4/14/05 <p>11) PMO# 47142: Scales</p> <ul style="list-style-type: none"> a. Removed the following scales according to CCP 2005-0345; WA# 17173, 17316, 17329, and 19839. b. Changed the tolerances for a test load of 1,000 kg from ± 0.5 kg to ± 1.0 kg for WA# 17268, 17334, 17357, 19829, 19830, 19833 and 36137 as per 2003 NIST handbook 44, Table #6 and Table # 1.1. c. Corner Load removed for tank scales WA 19830 and 36137 as per PPG-00009463 v.2. d. Reviewed MEIN form initiated by M. Aboyoun. Errors found on the HOR page Returned to maintenance on 4/21/05. e. 4/22/05: Correction made. Document reviewed. <p>12) PMO# 47144: Scales</p> <ul style="list-style-type: none"> a. Change the location of the following scales as per CCP 2005-0255; WA# 16966 and WA# 35088. b. Reviewed MEIN form and changes. c. Signed and forwarded to QA on 6/22/05 <p>13) PMO# 47142: Scales</p> <ul style="list-style-type: none"> a. Re-circulated: 7/5/05. b. Removed the following scales according to
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			<p>CCP 2005-0345; WA# 17173, 17316, 17329, and 19839.</p> <ul style="list-style-type: none"> c. Changed the tolerances for a test load of 1,000 kg from ± 0.5 kg to ± 1.0 kg for WA# 17268, 17334, 17357, 19829, 19830, 19833 and 36137 as per 2003 NIST handbook 44, Table #6 and Table # 1.1. d. Corner Load removed for tank scales WA 19830 and 36137 as per PPG-00009463 v.2. e. Reviewed MEIN forms initiated by M. Aboyoun. Error found on WA# 19833 MEIN form. Corrected by Stan Viau. f. Document reviewed. Forwarded to QA 7/5/05. <p>14) PMO# 47222: Room Pressure Monitor</p> <ul style="list-style-type: none"> a. Removed the following equipment according to CCP 2005-0344; WA# 80823, 80815, 36226 and 80821. b. Reviewed MEIN form initiated by M. Aboyoun. Errors found on the HOR page Returned to maintenance on 4/21/05. c. 7/5/05: Correction made. Document reviewed <p>15) PMO# 48079: HEPA Filter</p> <ul style="list-style-type: none"> a. Removed the following equipment according to CCP 2005-0341; WA# 80000, 80001, 80002, 80007, 80008, 80009, 80010, 80011, 80012, 80013, 80014, 80803, 80805, 80806, 80807 and 80808. b. Reviewed MEIN form initiated by J. Colas. c. 7/6/05: Reviewed PMO. Signed HOR. Forwarded to QA. <p>16) PMO# 59381: Hardness Testers</p> <ul style="list-style-type: none"> a. Hardness Testers with WA# 17010, 17034, 17041, 17663, 17668, 17679: corrected input/output range from 0 - 98.0 N / 0-
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				<p>Change Control (MEIN Form Changes)</p>
Ongoing		<p>Initiation of MEIN Forms for changes not requiring a Change Control</p>	Ongoing	<p>3355</p>
	<p>99.066 to 0 - 98.066 N / 0 - 98.066.</p> <p>Calibration Limits to include no decimal point to reflect actual data produced by the hardness tester.</p> <p>b. Hardness Testers with WA# 17037, 35430, 35431, 35432: corrected input/output range from 0 - 98.0 N / 0 - 99.066 to 0 - 98.066 N / 0 - 98.066. Calibration Limits to include one decimal point to reflect actual data produced by the hardness tester.</p> <p>c. Reviewed MEIN form initiated by A. Maciak. Current PMO not submitted for review. Changes justification not clear.</p> <p>d. Received on 7/29/05. Returned to maintenance for clarification and a copy of current PMO as a reference.</p> <p>e. 8/1/05: Documents resubmitted. 8/2/05: Signed and forwarded to QA (via S. Viaw).</p>			
	<p>1) MEIN Form "Fette Turrets WA# inscription".</p> <ul style="list-style-type: none"> Initiated: 03/23/2005 (CCP submitted) Change Control not needed. Existing equipment. MEIN forms submitted to M. Aboyoun (4/7/05) 			
	<p>2) MEIN Form "PC#8-DC departmental change."</p> <ul style="list-style-type: none"> Requested by Ed White. Error found on PMO Initiated: 04/06/2005 (Emergency CCP submitted) Changed department responsibility and person responsible. 			
	<p>3) MEIN Form for PMO# 47444: Scales (WA# 17319)."</p> <ul style="list-style-type: none"> MEIN form used to change the weight tolerance of a scale for 15kg scale change from 0.5 g to 15g and for 30kg from 0.5g to 30g Change corner load tolerance from 0.5g to 7.5g. Used 2003 NIST Handbook 44 table 1.1 for class 3 weighing devices Reviewed MEIN form initiated by M. Aboyoun 			

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			<ul style="list-style-type: none"> • Signed and forwarded to QA on 4/14/05 <p>4) MEIN Form for PMO# 47407: Scales (WA# 17175)</p> <ul style="list-style-type: none"> • MEIN form used to change the weight tolerance of a scale for 15kg scale change from 0.5 g to 15g and for 30kg from 0.5g to 30g. • Change corner load tolerance from 0.5g to 7.5g. Used 2003 NIST Handbook 44 table 1.1 for class 3 weighing devices • Reviewed MEIN form initiated by M. Aboyoun • Signed and forwarded to QA on 4/11/05 <p>5) MEIN Form for CTC PMO# 41207: Scales (WA# 35466)</p> <ul style="list-style-type: none"> • MEIN form initiated by J. Livolsi. Based on comments from the TPM team. • 41207: Removed sections for the Exhaust plenum seal, inlet plenum seals, door seals and pan seals. Team felt operators do these things. • 44056: Remove printer, felt operators check printer. PLC section removed steps 2 and 3. Team felt this would be detrimental to the PLC. Changed step 4 to read "remove any dust form cabinet with a vacuum." • Received 4/20/05. Left message for J. Livolsi. Returned call on 4/25/05. Set team made decisions. Said to speak to C. Defecianl. Did not agree with all changes C. D stated that no value added and based on PMO history all checked out OK • Reviewed MEIN form and signed 4/27/05 • Signed and forwarded to QA on 4/27/05 <p>6) MEIN Form for CTC PMO# 41208: Scales (WA# 35410)</p> <ul style="list-style-type: none"> • MEIN form initiated by J. Livolsi. Based on comments from the TPM team. • 41207: Removed sections for the Exhaust plenum seal, Inlet plenum seals, door seals and pan seals. Team felt operators do these things. • 44056: Remove printer, felt operators check printer. PLC section removed steps 2 and 3. Team felt this would be detrimental to the PLC. Changed step 4 to
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3357	Bin Storage Area Project	5/20/2004	Expand current South Vertical Cell Set-Up Shop and Washroom	<p>read "remove any dust form cabinet with a vacuum.</p> <ul style="list-style-type: none"> Received 4/20/05. Left message for J. Livolsi. Returned call on 4/25/05. Said team made decisions. Said to speak to C. Defeciani. Spoke to C. Defeciani. Did not agree with all changes C. Defeciani stated that no value added tests were removed, and based on PMO history all checked out OK Reviewed MEIN form and signed 4/27/05 Signed and forwarded to QA on 4/27/05 <p>7) MEIN Form for chart recorders on PMO# 59766: Recorders (WA# 92681 and WA# 92686)</p> <ul style="list-style-type: none"> MEIN form initiated by John Watkins c/o A. Maciak. Received on 5/27/05. Removed increasing and decreasing check points from Cal. Sheet and replaced this test with a single point calibration for temperature. Reviewed PMO. Change correct. Reviewed MEIN form and signed 5/27/05. Signed and forwarded to QA on 5/27/05. 6/15: Re-circulated for WA# 96281 and WA# 96286 added to the HOR page. Reviewed, initialed and forwarded to QA on 6/15/05. <p>8) MEIN Form for chart recorder on PMO# 47312: Recorders (WA# 17171)</p> <ul style="list-style-type: none"> MEIN form initiated by John Watkins c/o A. Maciak. Received on 5/27/05 Changed input range form 4-20 ma to 100 ohm RTD (0-100°F. Test points 10°F, 50°F, 90°F. Reviewed PMO. Change correct. Reviewed MEIN. Information on the MEIN form stated incorrectly. Corrected and initialed and dated by A. Maciak. Signed MEIN and forwarded to QA on 5/27/05. 	Project Scheduled for Completion: 1 st quarter 2005. Status: Project closed 2/10/05.
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		to accommodate new CTC equipment	effort, working with QA, updating any SOP(s), purchase of any new equipment and with working with the facilities manager, currently Andy Karc. 1) Meeting set for 5/26/04 to discuss the project scope 2) As project manager for the Bin Storage & Bin Warehouse projects: o Conducted meeting to review material project flow. o Met with Ram Shankar (project engineer) to establish project parameters o Established the project core team Ram Shankar-Engineering, Max Katz-Safety, Miraz Chowdhury-Tech. Service, Sal Calautti-QA o Conducted Material logistics flow Meeting on 9-14-04. ▪ Concluded this meeting establishing the material flow pattern for product and bin movement ▪ Meeting minutes written. Forwarded on 9-16-04 o Conducted Bin Storage/Bin Warehouse Project Meeting on 9-14-04. ▪ Established final design for Project Scope document approval. ▪ Meeting minutes written. Forwarded on 9-18-04 o Project document circulated. Reviewed, signed and sent to QA for approval (9-23-04) o 1/18/2005: ORR conducted (D. Siegel- Safety Department). No recommendations major. Project complete from a safety standpoint. o 2/10/2005: Change control closed. Area released to manufacturing for production purposes.	Deadline met.
33 Overall Development	5/20/2004	ITP% Tracking, Classes Taken, Special Training	1) ITP% ▪ As of 5/31/2005: 91% 2) Classes Training: ▪ Fette Training Levels 3, 4 and 9: 11/05.	Ongoing

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Project Name	Status
CTC System Software	<ul style="list-style-type: none"> ■ CTC Image of CTC#1: <ul style="list-style-type: none"> ○ Date due: 6/30/05 ○ Complete: 6/29/05 ■ CTC Risk Assessment: <ul style="list-style-type: none"> ○ Date due: 7/15/05 ○ Complete: E-mail forwarded 7/15/05. ■ Software delivered to J. Kozioł (7/12/2005). <ul style="list-style-type: none"> ○ All software delivered and will be placed in the Maintenance Library and the Engineering Software Library. Copies will be downloaded and placed on the LAN. ■ CTC Image download for spare computers <ul style="list-style-type: none"> ○ Quote received from Vendor ○ WO# 1095891 initiated for work. Must be capitalized, per V. Rappa. Request will be forwarded to the Engineering Support group.
PMO Review	<ul style="list-style-type: none"> ■ June Status: Sign off % = 83.0% <ul style="list-style-type: none"> ○ 47 PMO listed. 37 signed. ■ Reviewed PMO# 40009 to close CCP 2005-0397. Errors found. Returned to Maintenance. <ul style="list-style-type: none"> ○ Corrected forwarded to QA (7/15/05) ■ Reviewed PMO# 62019 to close CCP 2004-1168. Errors found returned to maintenance <ul style="list-style-type: none"> ○ Corrected forwarded to QA (7/15/05)
Maintenance Zone Checklists	<ul style="list-style-type: none"> ■ Notifications sent to remind staff to conduct audit <ul style="list-style-type: none"> ○ 7/6/05: ■ Clarence "Ed" Evans on vacation. Reported to A. Espejo. Zone #27 reassigned to Seam McGarvey. <ul style="list-style-type: none"> ■ All Zones complete. ■ Forwarded to A. Espejo (7/8/05) ○ 7/13/05: <ul style="list-style-type: none"> ■ Notification sent. ■ Zones audited and collected. ■ All checklists submitted and signed off by 7/15/05. ■ Forwarded to A. Espejo (7/25/05) ○ 7/20/05: <ul style="list-style-type: none"> ■ Notification sent. ■ Zone audited and collected ■ All checklists submitted and signed off by 7/25/05 ■ Forwarded to A. Espejo (7/25/05)
Blender Turner Support	<ul style="list-style-type: none"> ■ Littleford 8K Blender (5-24-05: 10 min blend) <ul style="list-style-type: none"> ○ Requested by: Alice Grass (6-07-05) ○ Batch#: Centrum-4451-A097703 ○ Supplied: 6/08/05 ■ Littleford 8K Blender (5-24-05: 1 min blend) <ul style="list-style-type: none"> ○ Requested by: Alice Grass (6-07-05) ○ Batch#: Centrum-4451-A097703 ○ Supplied: 6/08/05 ○ Batch#: Centrum-4451-A097703

Project Summary (July 2005)

<ul style="list-style-type: none"> ■ CCP 2005-0672 "Ajax Shaker" Buna-N Nitrile Rubber. Specifying that the material is food grade. ○ Initiated: 7/07/2005. Verbal approval (7/6/2005)-G. Keaney. ○ Approved: 7/11/2005. ○ Closure due date: 11/11/2005 ■ CCP 2005-0662 "Change SOI to read 3/16" plate from it reading a 1/4" plate." Done for Centrum@ Export and Centrum@ Silver Accela-Coater and Pan Coater batches. ○ Initiated: 7/06/2005 ○ Approved: 7/12/2005 ○ Closure due date: 9/21/2005 ■ CCP 2005-0637 "Change SOI to read 3/16" plate from it 	Change Control Procedures
<ul style="list-style-type: none"> ■ Ajax Shaker Gasket Repair: <ul style="list-style-type: none"> ○ 7/6/05: Investigate and inspect unit. Assess tear. Unit must be repaired cannot run. Shaker must be shutdown. ○ WO# 1095592 initiated. ○ Unit taken apart. ○ Gasket delivered 7/7/05. Unit repaired. ■ Fette Spare Parts Info <ul style="list-style-type: none"> ○ List given to P. Boykin for price confirmation and lead-time. List returned. ○ List forwarded to group. Meeting set up (7/28/2005). ■ Blender 10K blender plow repair coverage: <ul style="list-style-type: none"> ○ Coverage provided 3 pm - 11 pm shift (7/20/05). ○ Badge# 104178: transferred from Keith Anderson to Kathy Gunsen. Badge# 30431: Held by Rich Haenssler returned to maintenance. ○ Issued permits and inspected job site periodically ■ PC#9 Upgrade project: <ul style="list-style-type: none"> ○ Coverage provided 3 pm - 7 pm ○ Issued permits and inspected the job site at the end of the day. ○ Returned badges. Badge# 30430 & Badge# 30577, held by K. Wilson and K. Tomjanovick of Thomas Engineering, returned to maintenance. ■ DI Water System Coverage 7/20 - 7/26/05 <ul style="list-style-type: none"> ○ O3 generator shutdown. ○ WO# 1097661 issued. Compressed air line damaged. Repaired by M. Martinez. 	Production Support
<ul style="list-style-type: none"> ○ Supplied: 6/08/05 ■ Gemco 30: 130/510 (6-8-05: 40 min blend) <ul style="list-style-type: none"> ○ Requested by: Skip Gremli (7-05-05) ○ Batch#: Fibercon-2500-B04605 ○ Supplied: 7/07/05 - Blender in use 7/6/05 AM / PM ■ Gemco 30: 130/510 (6-8-05: Blend Times: 5:42 pm - 6:21 pm) <ul style="list-style-type: none"> ○ Requested by: Skip Gremli (7-05-05) ○ Batch#: Fibercon-2500-B04603 ○ Supplied: 7/07/05 - Blender in use 7/6/05 AM / PM ○ Shifts. Down 7/7/05 ○ Shifts. Down 7/7/05 	

<p>Commitments</p>	<ul style="list-style-type: none"> ■ PR #89211 "Installation of new 3/16" screen in the Ajax Shaker" <ul style="list-style-type: none"> ○ Due date: 5/31/2005 ○ New screen installation attempted by K. Flowers. ○ Screen would not fit. (5/20/05). ○ Screen inspected. W/O# 1080949 initiated to modify the screen (5/25/05). ○ Commitment extended for 3 months so that installation could take place. ○ CCP 2005-0510 initiated for change. Change complete CCP closed. ○ Closure documents submitted. Closed (7/20/05) ■ PR #107328: Evaluate possibility of putting door sweep on doors. <ul style="list-style-type: none"> ○ Due date: 9/08/05 ○ Discussed situation with F. Erichsen. W/O# 1087975 initiated to investigate if request is
<p>Tablet Optimization</p>	<ul style="list-style-type: none"> ■ Tablet Hoe Implementation <ul style="list-style-type: none"> ○ Devices ordered. Broke after first day of use. Alternative designed, W/O# 498973 initiated. Initial design not feasible. ○ Re-enforcement design adopted. QA reviewed change ○ 7/12/05: Verbal approval via QA to use rakes on a temporary basis. If design is used, CCP to be initiated.
<p>Special Requests</p>	<ul style="list-style-type: none"> ■ Littleford 10K SOI Check: <ul style="list-style-type: none"> ○ Check SOI to ensure 1 min blend is in the SOI. ○ Contacted Document Control to obtain all Centrum 10K SOI documents. ○ Reviewed documents to confirm 1-min blend. ○ Complete: E-mail sent confirming SOI has 1 min blend. ■ FRM check for procedure that may be used to clean portable Mixer <ul style="list-style-type: none"> ○ GXPPharma check ○ FRM-00002849 entitled "Coating Solution Tank Cleaning found ○ Forwarded to the group
	<ul style="list-style-type: none"> ■ CCP 2005-0584 "Chile modifications for press WA# 33 192 and 34887" <ul style="list-style-type: none"> ○ Initiated: 6/10/2005 (Emergency CCP submitted. ○ Change implemented 6/9/05 ○ QA approval 6/10/05 (G. Kearney) ○ Approved: 6/20/2005 ○ Closure due date: 9/20/2005 ○ Closed: 6/30/2005 ○ Initiated: 6/29/2005 ("RUSH" CCP submitted). Walked document around for signatures ○ Approved: 7/01/05 ○ Closure due date: 8/03/2005

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<p>Work Order</p> <p>Initiation/Management</p>	<ul style="list-style-type: none"> ○ Door sweeps found in door. Added full length ○ curtains. Work Complete: 7/18/05 ○ Closure documents submitted: 7/19/2005. ○ Closed by QA: 7/20/05 ■ PR #111134: CTC By-Pass Training ○ Due date: 7/29/2005 ○ Create slides for training operators on the ○ functionality of the By-Pass, Resume and Pause ○ modes for the coater (1.5 hr) ○ All CTC operators trained on the By-Pass Training (7/21/05). ■ Midnight shift: 6 am ■ Day Shift: 7:30 am ■ Afternoon Shift: 3:15 pm ○ Iso-train documents scanned into Trackwise for closure. ○ Forwarded and closed by QA (7/25/05) ■ Work order initiation: ○ 357 initiated for the fiscal year.
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Below is a brief summary of some of the tasks achieved during the month of July. Thank you and please contact me if you have any questions.

[illegible]

- Special projects after hours coverage;

- Notified security and the fire department that the job ended for the day.
- Collected Badges of K. Wilson and T. Tomjanovick. Submitted the V. Rappa
- Emailed V. Rappa regarding time contractor left the job site.

- CTC Cleaning Verification:

- Successful execution of Study Plan 640-009-LQ-03, assessing CTC #1 (WA#35466) for cleanliness after a 30 day campaign. No deviations found (7-19-05).

- Final report circulated and approved (7-22-2005). CTC released to production for use.

- Provided Blender Timer Report Printouts for the following equipment:

- Gemco 30: 130/5/10 (6-8-05; 40 min blend)
- Requested by: Skip Gremll (7-05-05)
- Batch#: Fibercon-2500-B04605

- Gemco 30: 130/510 (6-8-05: Blend Times: 5:42 pm – 6:21 pm)
 - Requested by: Skip Gremil (7-05-05)
 - Batch#: Fibercon-2500-B04603
 - Supplied: 7/07/05 –Blender in use 7/6/05 AM / PM Shifts. Down 7/7/05
 - Commitment Information:
 - Commitment: PR# 89211 "Screen with Smaller Holes for 8K"
 - Due date 8/31/05.
 - CCP 2005-510 initiated 5/20/05 (Emergency CCP)
 - Approved: 5/20/05
 - Change complete. Closure documents submitted 7/19/05.
 - Commitment closed 7/20/05.
 - Commitment PR #90042: Evaluate the feasibility of re-engineering the lock-in pin on valve
 - Due date: 9/20/05
 - Vendor contacted to provided plan and quote to redesign the valve
 - 7/26/05: Quote received
 - Vendor contacted about quote.
 - 8/2/05: Memo written assessing quote and feasibility of redesign proposal.
 - Documents submitted for closure (8/3/05).
 - Closed (8/3/05)
 - Commitment: PR# 107328 "Evaluate possibility of putting a door sweep on doors":
 - Due date 9/08/05.
 - WO# 1087975 initiated 6/9/05 to investigate possibility of installing a door sweep.
 - Investigated by carpenter. Door sweeps already in place. Gaskets replaced. Full length curtains installed
 - WO completed: 7/18/05

4520

1291

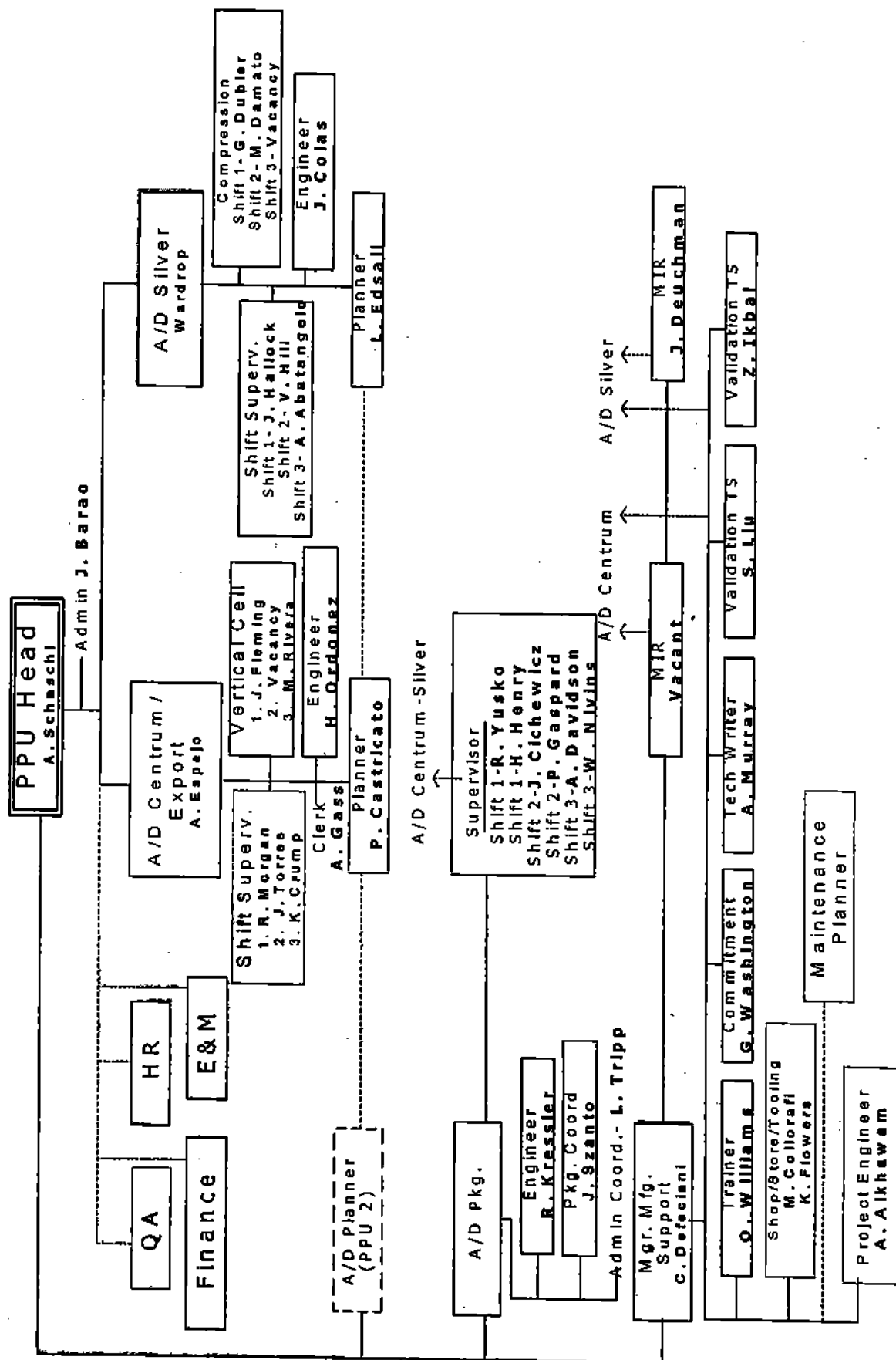
- Completed WO submitted for closure (7/19/05)
- Commitment closed 7/20/05.
- PR # 111134: CTC By-Pass Training
 - Due date: 7/29/2005
 - All CTC operators trained on the By-Pass Training (7/21/05).
 - Midnight shift: 6 am; Day Shift: 7:30 am; Afternoon Shift: 3:15 pm.
 - Iso-train documents scanned into Trackwise for closure.
 - Forwarded and closed by QA (7/25/05)
- Monthly PMO (Status and Completion):
 - Performed the following duties to complete this task
 - Create spreadsheet (07-08-2005).
 - Track PMO, sign off and completion for the month.
 - Sign off completion percentage: 85.7%
- Change Control Information:
 - CCP 2004-1168: "Comprima Project-Modification of Compression Room W (112-310)"
 - Initiated: 8/16/2004 (Joe Torres)
 - Contacted vendor for updated coil and AHU documents. Faxed documents to vendor.
 - Received faxed documents from vendor on 10-09-04
 - Original closure due date: 3/1/2005
 - Amendment closure due date: 7/18/2005
 - CCP closed: 7/18/2005
 - CCP 2005-0397 "Stokes 754 Motor Change"
 - Initiated: 04/07/2005 (Emergency CCP submitted)
 - Approved: 04/18/2005.
 - Closure due date: 7/18/2005
 - CCP closed: 7/18/2005.
 - CCP 2005-0510 "Installation of 3/16" Screen for Ajax Shaker"
 - Initiated: 5/20/2005 (Emergency CCP submitted)

4522

- CCP walked around. Approved in one day.
- Approved: 5/20/2005
- Original closure due date: 6/3/2005
- Amendment closure due date: 8/31/2005
- CCP Closed: 7/21/2005
- CCP 2005-0672 "Ajax Shaker" Buna-N Nitrile Rubber.
- Initiated: 7/07/2005. Verbal approval (7/6/2005)-G. Keaney
- Approved: 7/11/2005
- Closure due date: 11/11/2005
- CCP closed: 7/29/2005
- Investigated Compressed Air 100 Complex Outage Request:
 - E-mail sent by M. Katz on 07/20/05 @ 3:54 pm.
 - Discussed situation with Glen Powers and Sean McGarvey (temp supervisors). Both stated that PPU#1 compression was down. PC#9 running (G. Powers). Unit stopped (Low air alarm), shut off by operator, restarted, no product impact.
 - Discussed situation with Lou Baldi (PPU#3 supervisor). Stated that PPU#3 compression was down. PC#1 running. Unit shut down, stopped by operator, restarted, no product impact.
 - Response e-mailed sent @ 8:13 pm.
- Special operator requests:
 - Increase roller protection for drum carts used in CTC#1 (7/20/05)
 - Requested by operator J. Rosado. Need to mimic design of drum carts used in CTC#2.
 - WO#1097287 initiated to fix stainless steel plate.

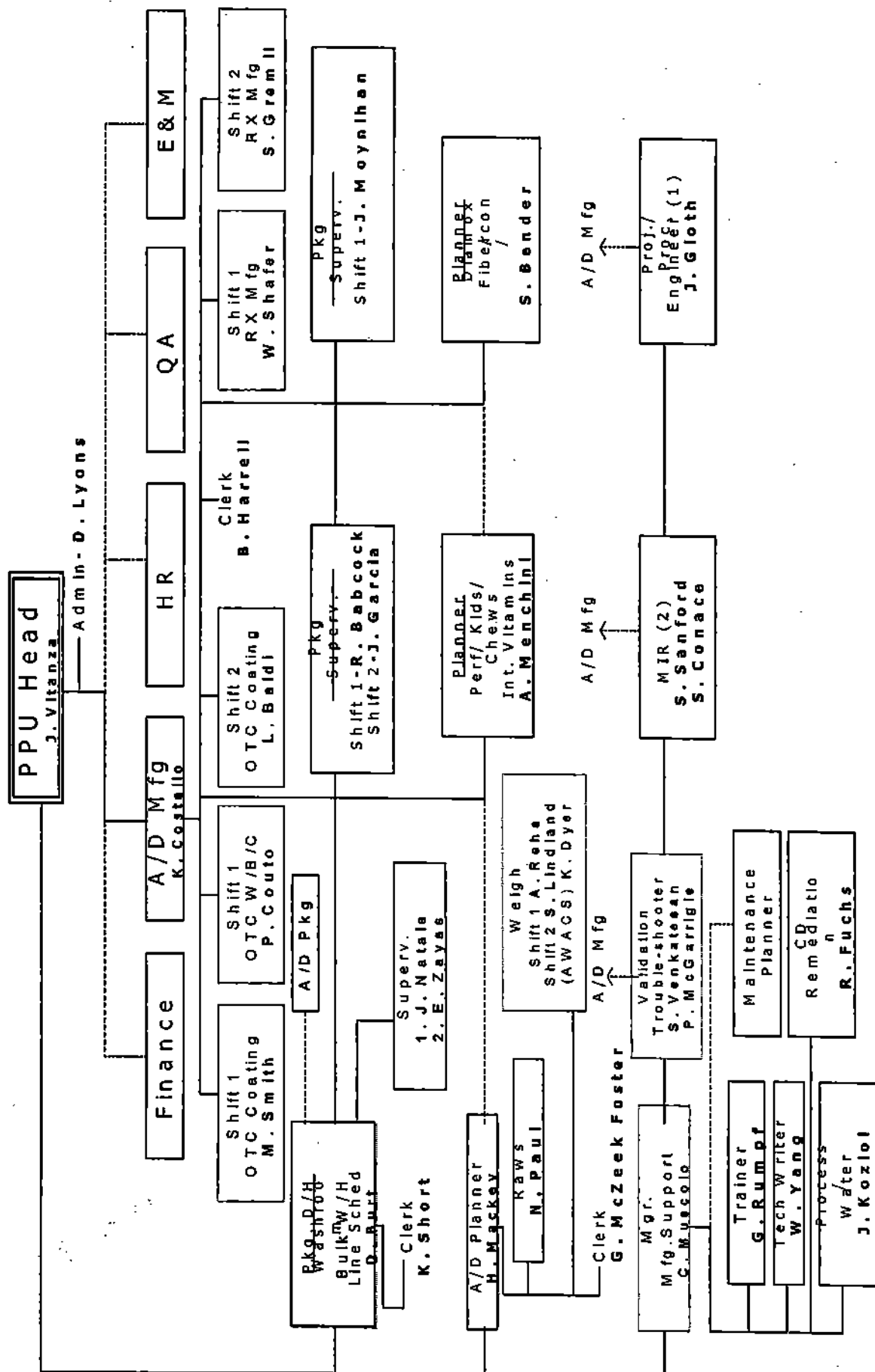
PPU-1

Centrum, Export, Silver

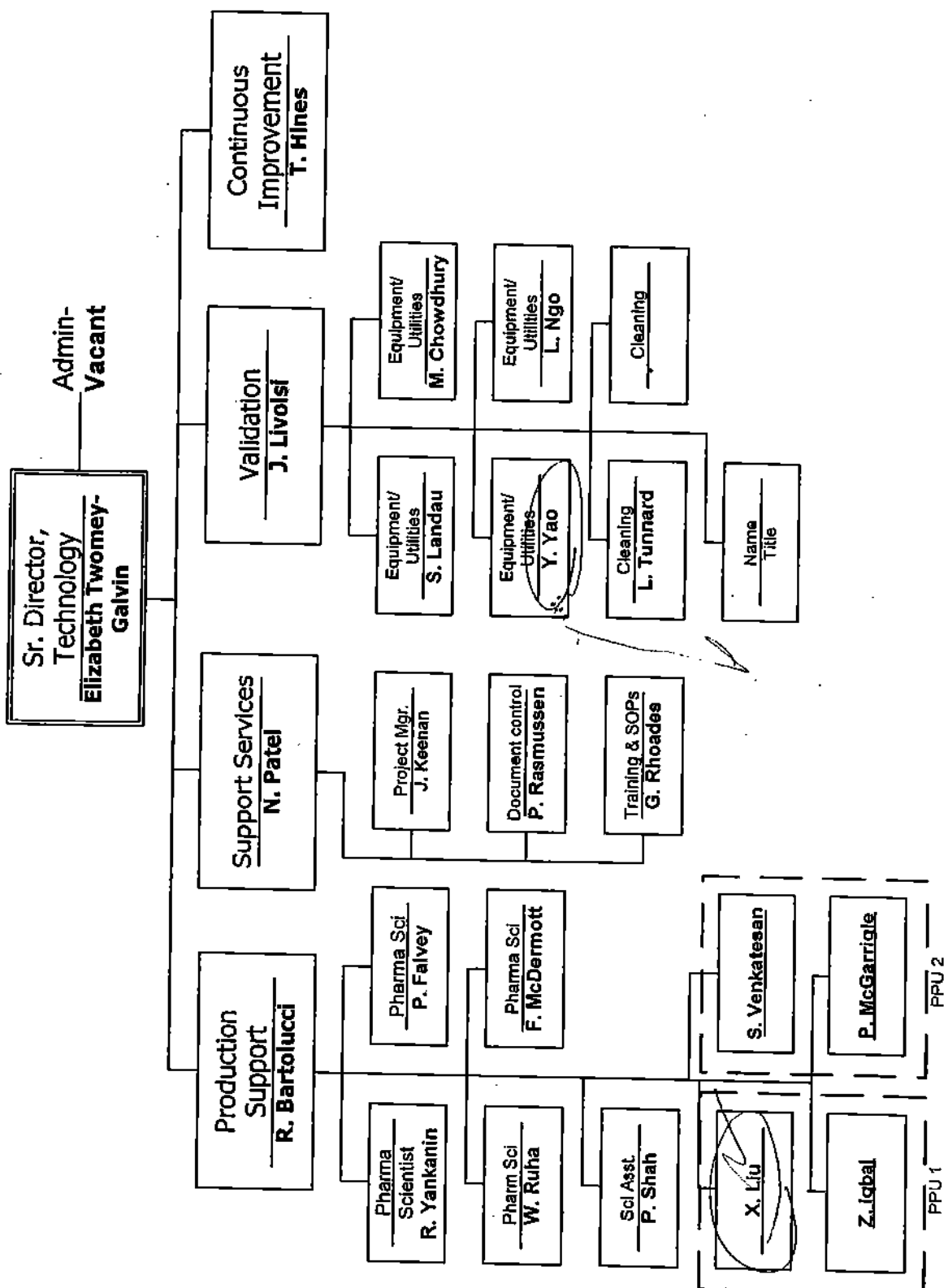


PPU - 2

Performance, Int'l Vitamins, Kids/Adults, Fibercon, Diamox



Technology Organization Structure



From: N P <newtonpaul3@yahoo.com>
Sent: Monday, October 17, 2005 6:19 pm
To: howieh04@optonline.net
Cc:
Bcc:
Subject: Wyeth Info 1

[Print E-mail](#)

Internal Correspondence

Date: October 10, 2005

To: All Pearl River Employees

From: Joe Vitanza, Managing Director, WCH

Subject: Organizational Changes in Consumer Health
Manufacturing/Packaging

I am pleased to announce the following changes to the Pearl River Wyeth Consumer Healthcare Manufacturing and Packaging organization. The changes were undertaken to achieve the efficiencies developed during the "Excellence in Operations" initiative. In addition, they will provide cross-functional career development opportunities and will support the transition to a lean manufacturing/packaging "pull system" operation.

Consumer Health Management Team

Walter Wardrop is appointed Director, Packaging and Planning. Walter previously held the position of Director, Centrum PPU.

Andrew Espejo is appointed Director, Centrum PPU. Andrew previously held the position of Project Director, Lean Manufacturing.

Monte Bradford has been transferred to Director, Operations Planning, reporting to Paul Hennessey, Nutritionals Strategic Category Leader. Monte previously held the position of Director, Packaging and Planning.

Kevin Costello, Director, Performance PPU; Fred Kilpatrick, Senior Director, Technology and Elizabeth Comey-Galvin, Senior Director, Lean Manufacturing, will continue to report to Joe.

**Consumer Manufacturing and Packaging
Centrum PPU**

Christopher Defeciani is appointed Production Manager (Days), Centrum PPU. Chris previously held the position of Manager, Production Support Centrum PPU.

Jennifer Hallock has been appointed Production Manager (Evenings), Centrum PPU. Jennifer previously held the position of Production Supervisor.

Thomas Rock has been appointed Compression Shop Supervisor, Days. Tom was previously a Production Operator and Temporary Supervisor.

Pierre Gaspard has been appointed Weighing Supervisor, Evenings. Pierre previously held the position of Supervisor, Packaging.

Brenda Harrell has transferred to Administrative Assistant, Centrum PPU. Brenda previously held the position of Administrative Assistant in the Performance PPU.

Diane Brady is appointed Compliance Specialist (Evenings). Diane previously held the position of Project Specialist in WCH Quality Assurance.

Performance PPU

Dan Ferry has been appointed Production Manager, Performance PPU. Dan previously held the position of Assistant Director of Manufacturing & Pharmacy at Solgar Manufacturing.

Nitiksha Patel has been appointed the position of Manager, Manufacturing Support, Performance PPU. Nikki previously held the position of Project Manager, Technology.

Grace Rhoades has been appointed the position of Trainer/SOP Coordinator in the Performance PPU. Grace previously held the position of Document Associate II in WCH Technology.

Paulo Couto has been appointed the position of Water System Engineer/AWACS Administrator. Paulo previously held the position of Production Supervisor, Performance PPU.

Jozef Koziol has been appointed the position of Project Engineer. He previously held the position of Water System Engineer.

Kathy Short has been appointed the position of Administrative Assistant, Performance PPU. Kathy previously held the position of Administrative Assistance in the Bulk Warehouse area.

Packaging/Planning

Francis McDermott has been appointed the position of Packaging Manager. Francis previously held the position of Senior Pharmaceutical Scientist, Technology.

Kathy Dyer has been appointed the position of Supervisor, Packaging. Kathy previously held the position of the AWACS System Administrator.

Keith Crump has been appointed the position of Supervisor, Packaging. Keith previously held the position of Training Specialist in the Centrum PPU, Technology.

Cara Muscolo has been appointed the position of Manager, Project Management. Cara previously held the position of Manager, Manufacturing Support, Performance PPU.

Greg Rumpf has been appointed the position of Project Manager, Technology. He previously held the position of Sr. Training Specialist in the Performance PPU.

Margaret O'Toole has been appointed Associate Director, Validation in Technology. Margaret previously held the position of Associate Director, WCH Engineering/Maintenance.

Lean Manufacturing

Dave Quinones has been transferred from the Business Process Management group to the Consumer Health Factory reporting to Elizabeth Twomey-Galvin, Sr. Director, Lean Manufacturing.

Please join me in wishing them all continued success in their new positions.

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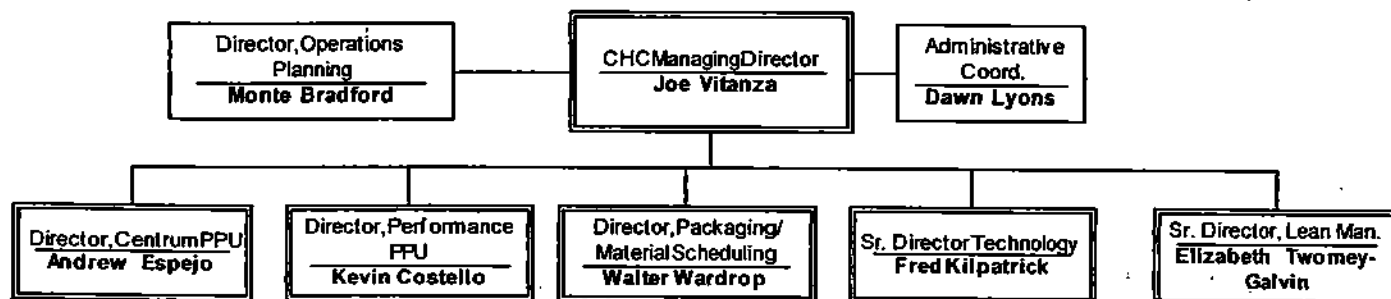
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Wyeth

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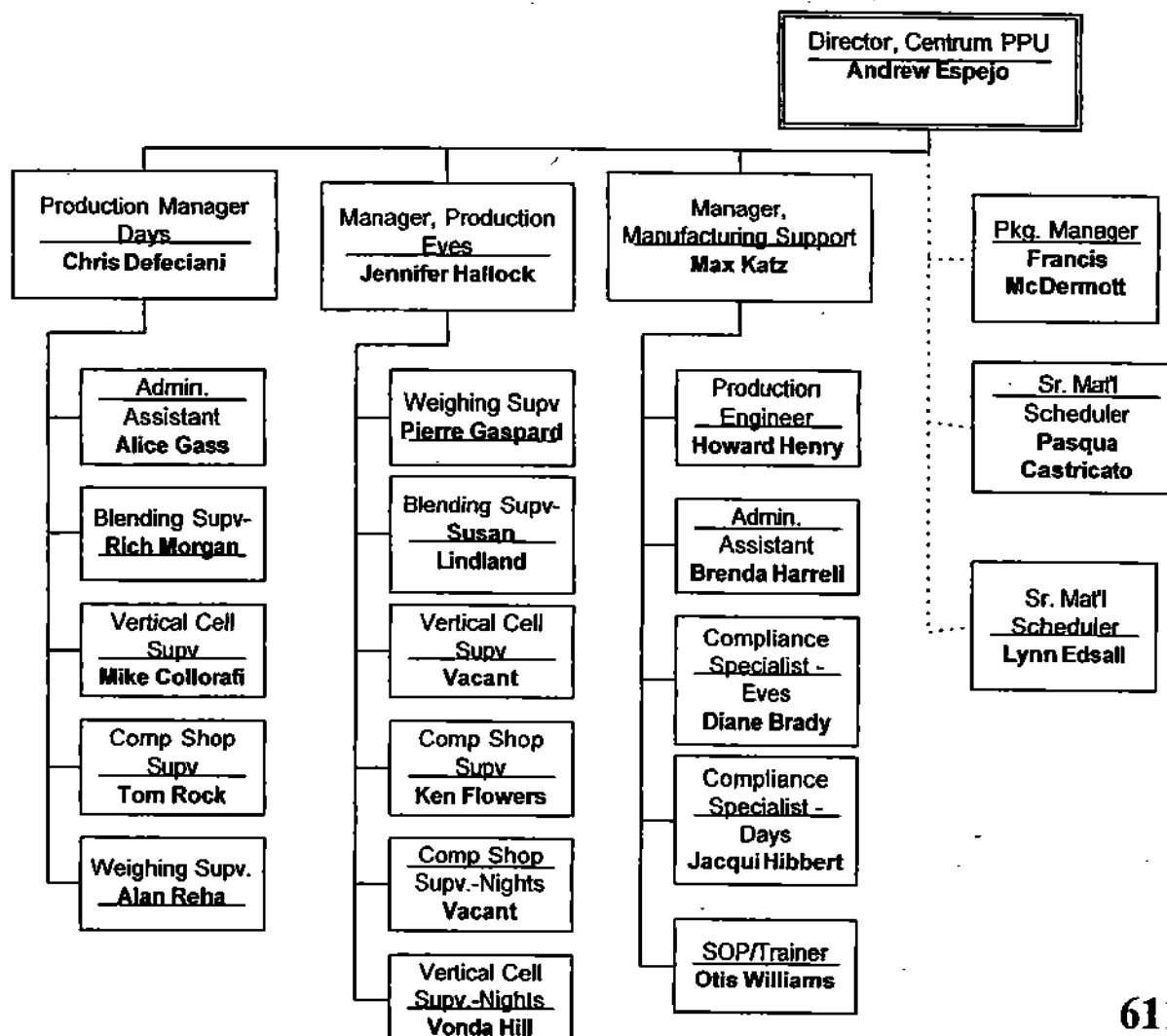
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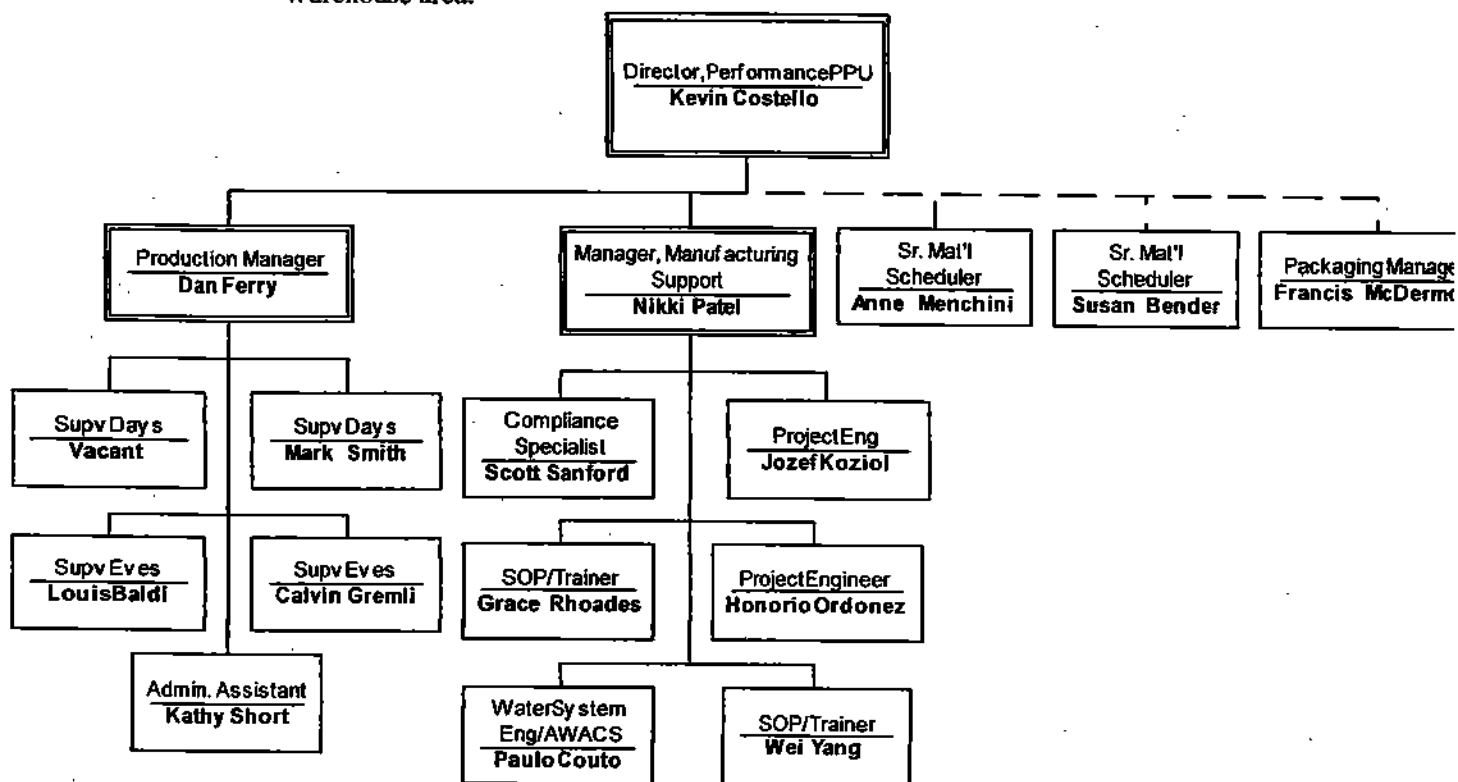
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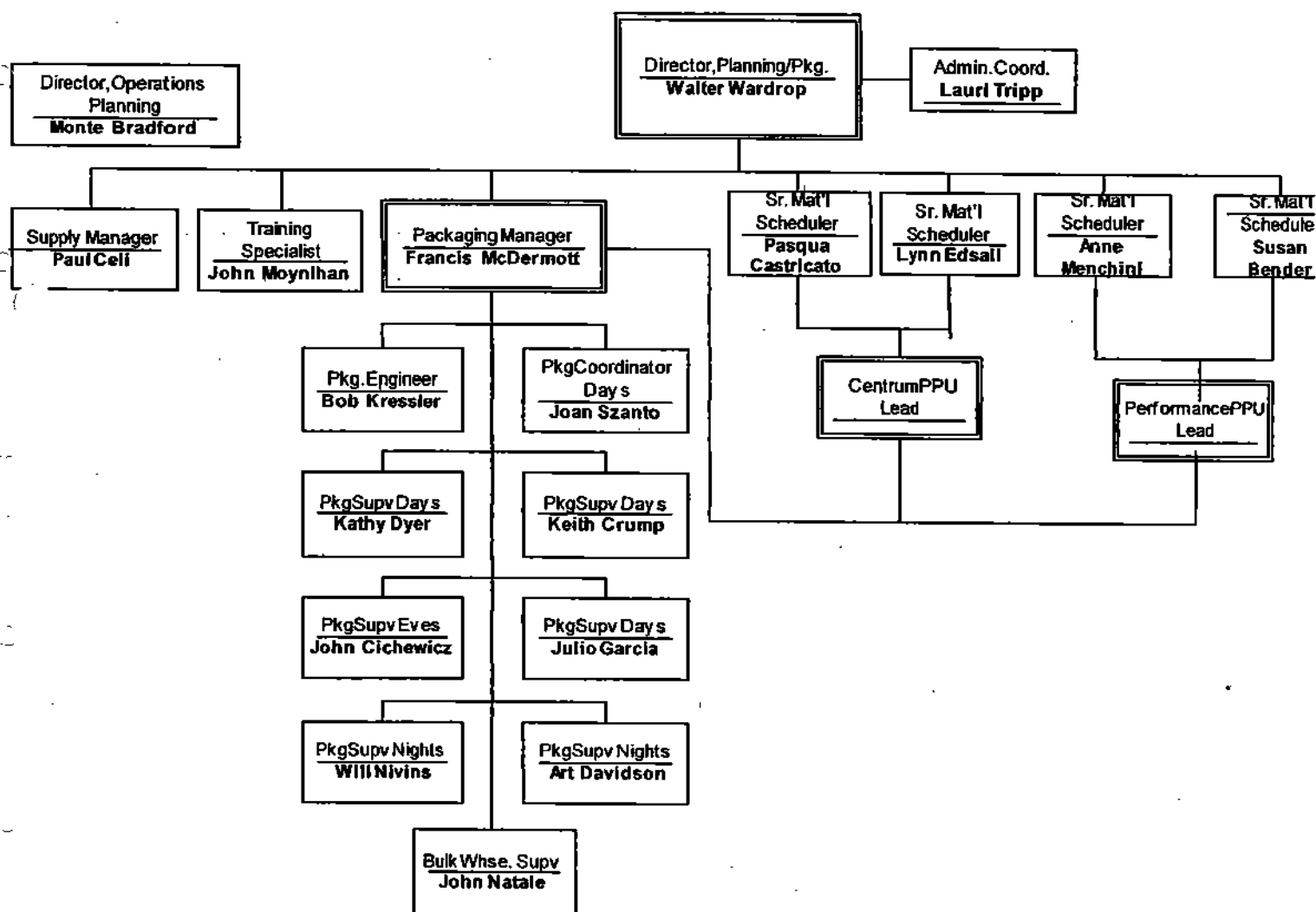


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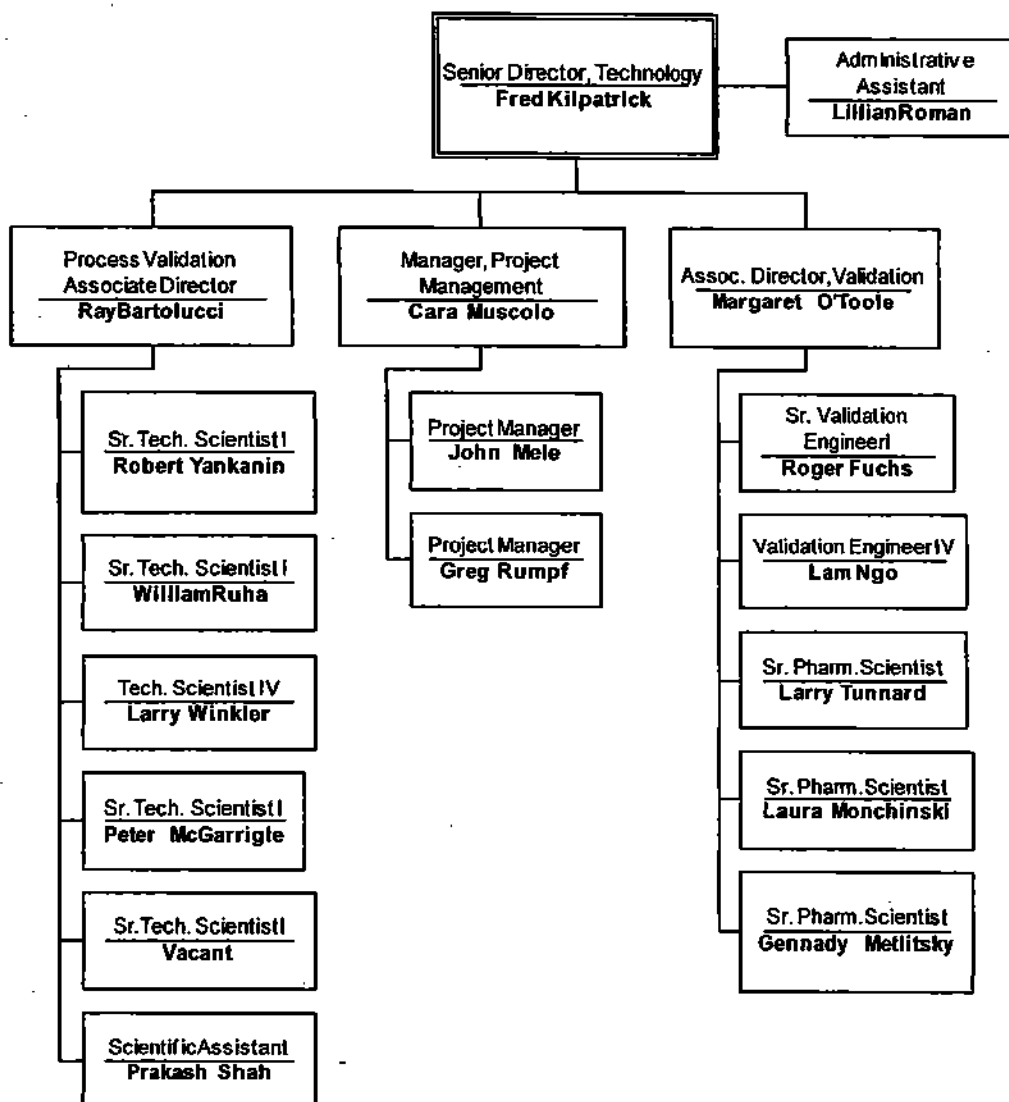


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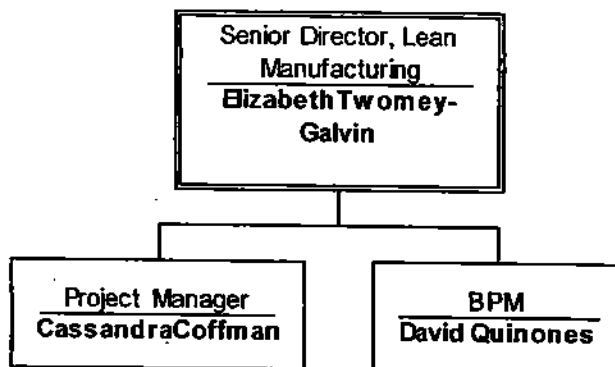
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